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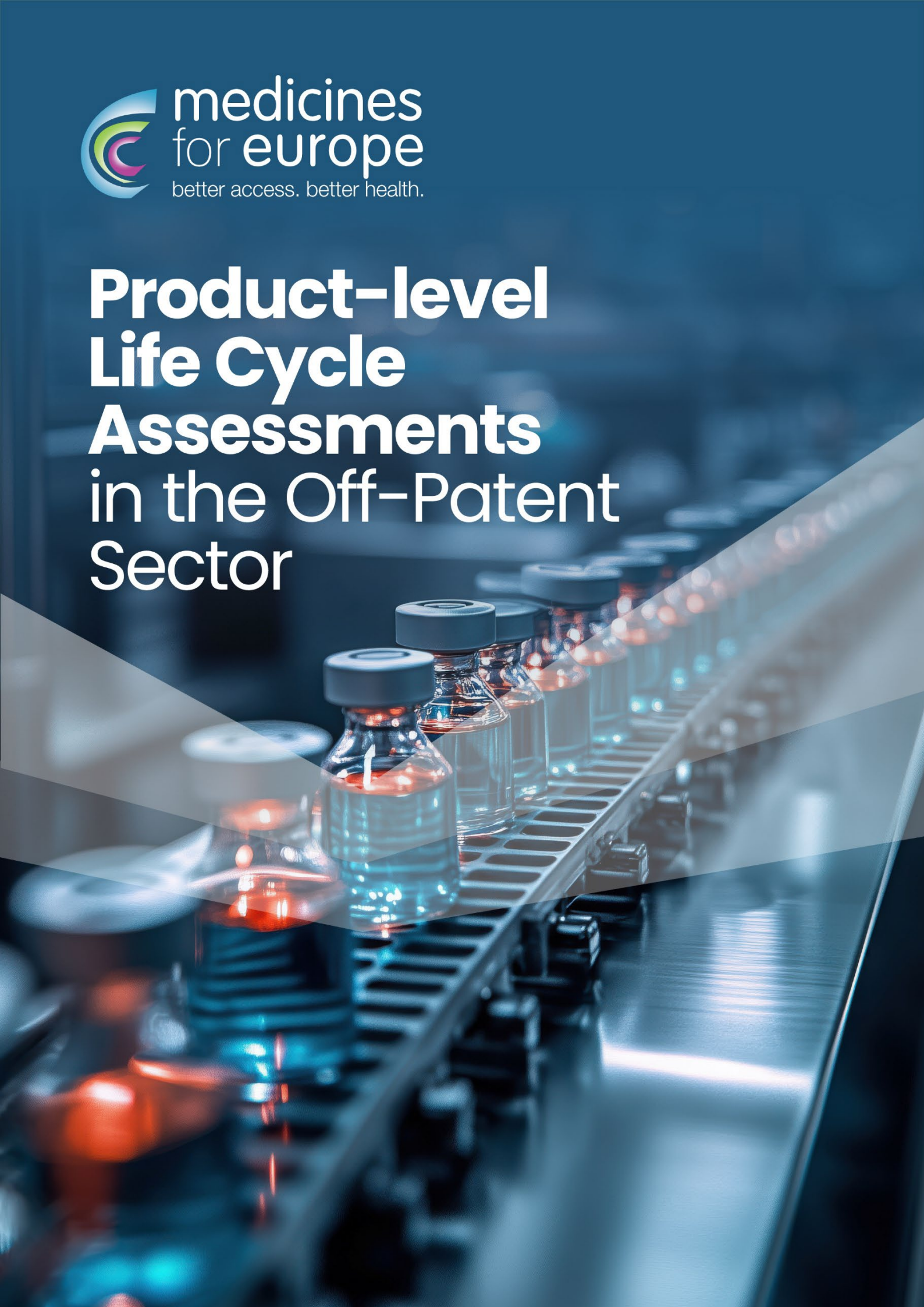
Product-level Life Cycle Assessments in the Off-Patent Sector



Executive Summary

Medicines for Europe, representing the off-patent pharmaceutical sector, is **committed to environmental sustainability while ensuring access to affordable, high-quality medicines**. The industry recognises the need to build climate change resiliency and reduce environmental impact - including reducing greenhouse gas emissions, and supports practical, science-based approaches aligned with EU Green Deal objectives.

Companies in the off-patent sector work systematically to reduce environmental impact while upholding access to a broad portfolio, typically implementing and tracking efforts on the company, site and process level. Flexibility in manufacturing facilities is a fundamental design feature that supports supply chain resilience, especially among off-patent manufacturers with large and diverse portfolios underpinned by the global supply chain. As a single factory can manufacture multiple products, and capacity is often swapped between products depending on demand, attributing a carbon footprint to an individual product is not feasible.

While product-level **Life Cycle Assessments** (LCAs) can offer relevant insights in specific contexts, they are not suitable tools for regulatory decision-making in approving a medicine or selecting a medicine. Moreover, **applying LCAs at the product level in the off-patent sector is both impractical and potentially harmful**. The off-patent industry's broad, complex product portfolios that vary per markets/ geographies, depend on an often global and diverse supply chain, narrow margins, and existing regulatory obligations, making comprehensive LCAs unfeasible and disproportionately burdensome. Challenges such as inaccessible and incomparable data, supply chain diversity and flexibility, and misalignment with clinical and regulatory realities further limit the validity of product comparisons based on LCA results. Over-reliance on product-level LCAs **risks fragmenting sustainability efforts**, leading to surface-level compliance rather than meaningful environmental progress.

Medicines for Europe proposes a more effective and proportionate alternative**: a risk-based, company- or manufacturing site-level compliance approach**, aligned with **existing EU environmental frameworks**. This strategy allows resources to be targeted where the greatest effect can be achieved to reduce environmental impact, without compromising medicine supply or affordability.

In procurement, the integration of **Green Public Procurement** (GPP) principles should be guided by standardised, verifiable environmental criteria that reflect the realities of generic manufacturing. **MEAT (Most Economically Advantageous Tender) criteria** related to sustainability should focus on carbon reduction, responsible waste and water management, AMR mitigation, and recognised international standards such as ISO 14001 and SBTi. In the specific case of antibiotics, the sector advocates for the AMR Industry Alliance's Common Antibiotic Manufacturing Standards, including environmental targets and independent certification schemes.

To conclude, the off-patent medicines sector is fully committed to sustainability and is investing for tangible improvements. However, sustainability policies must be feasible, proportionate, and tailored to the realities of the off-patent sector. Medicines for Europe urges policymakers to **adopt pragmatic approaches that promote environmental progress while safeguarding affordable access to essential medicines across Europe**.

Introduction

As representatives of the off-patent pharmaceutical sector, our mission is clear: **ensuring broad access to affordable, high-quality medicines while integrating sustainability into our operations**. Medicines for Europe recognises that human and environmental health are interconnected, and the off-patent industry is committed to minimising its environmental impact while safeguarding a reliable supply of essential medicines. Off-patent medicines account for around 70% of all medicines dispensed in Europe, making this sector a cornerstone of both access and sustainability efforts in healthcare.

The integration of a **product lifecycle assessment** (LCA) **into pharmaceutical policy and frameworks** must be carefully designed to avoid unintended consequences that could compromise the affordability and availability of medicines. **A balanced approach** is essential, one that promotes environmentally responsible practices without jeopardising patient access or increasing healthcare costs.

Medicines for Europe has consistently demonstrated its **commitment to sustainability** by actively supporting key EU initiatives under the Green Deal, such as the Pharmaceutical Strategy and the Zero Pollution Action Plan to advance sustainable and affordable access to

medicines. Member companies of Medicines for Europe are fully committed to working with policymakers **to deliver practical, science-based solutions** for a more environmentally sustainable pharmaceutical sector.

This position paper outlines Medicines for Europe's perspective on integrating environmental considerations into procurement and regulatory frameworks, emphasising the need for a **proportionate, feasible, and science-driven approach that promotes both** environmental **sustainability across the pharmaceutical supply chain and patient access to medicines.**

The limited feasibility of product-level LCA in the off-patent space

Mandating comprehensive **product-level Life Cycle Assessments** (LCAs) for every single generic medicine (or even Stock Keeping Unit, i.e. SKU) is not only impractical, but **counterproductive and potentially detrimental to access to medicines**. The off-patent pharmaceutical industry, which ensures access to thousands of essential and affordable medicines across Europe, operates under unique structural and economic constraints. A product-level approach is **misaligned with the realities** of the off-patent pharmaceutical sector, and risks diverting resources from more impactful, scalable strategies. The following points outline the key structural, operational, and regulatory challenges that make product-level LCAs an ineffective and unsustainable approach for the generic medicines sector. Further, LCA data can become dated quite rapidly as supply chains and value chains for a product are modified.

Data and Supply Chain Challenges

Generic pharmaceutical manufacturers operate within intricate, globalised supply chains involving numerous suppliers, intermediaries, and manufacturing sites. These networks are often decentralised and span multiple jurisdictions, making the systematic **collection of accurate, product-specific life cycle data exceedingly challenging**. Crucial primary data are frequently proprietary or controlled by third parties that often commercialise such information, making **access both costly and administratively complex**. Attempting to

retrieve and standardise this data would require significant effort as well as substantial financial investment, disproportionately burdening off-patent industry companies already operating within limited margins.

Moreover, the **use cases for current and emerging LCA methodologies** in the pharmaceutical sector **remain unclear**. These approaches fail to account for the fact **that selecting one medicine over another based on LCA results is fundamentally inappropriate**, given the clinical and regulatory complexities that govern pharmaceutical use. Noting that, even if a standard exists, meaningful comparison between products would still not be feasible due to inconsistencies in input data. The mix of primary, secondary, and proxy data used at different life cycle stages may be verifiable, but it is not comparable, making product-based ranking or selection unreliable and potentially misleading.

Generic medicines are developed by replicating a brand-name medicine after its patent expires, a process involving market analysis, formulation development, and the creation of robust analytical methods to ensure the generic product is therapeutically equivalent and bioequivalent to the original. The process typically involves extensive bioequivalence studies, manufacturing process validation, and rigorous regulatory review to demonstrate that the generic drug's quality, safety, and effectiveness are the same as the brand-name version. Meaning that generic medicines have regulatory constraints to the ability to deviate from the originator product, as well as significant cost barriers. Hence, even if an LCA would help identify new opportunities to reduce the environmental impact, the generic manufacturer may not be able to make such changes. Introducing product-level LCAs imposes yet **an additional layer of complexity**, demanding a different type of data, without delivering proportionate sustainability benefits.

Ultimately, the frequent changes in suppliers, manufacturers, and raw materials, a common feature of generic pharmaceutical production, create significant complexity and make accurate, up-to-date data difficult to access. This dynamic supply chain environment would require LCAs to be revised regularly, reducing operational flexibility and significantly increasing costs. Combined with the duplicative burden on already regulated entities, these challenges severely compromise the reliability, consistency, and practical usability of product-level LCAs. As a result, this structural reality questions the suitability of LCAs as a regulatory tool for the off-patent pharmaceutical sector.

Scale, Complexity, and Cost

Generic manufacturers are responsible for producing and supplying thousands of different medicines in Europe. Individual companies can hold portfolios of thousands of medicines, typically unique for each country, to allow for more optimal treatment. Off-patent medicines are often procured via public procurement and tender processes that have limited foresight on the products in scope, short timelines (1-3 months) and low prices. Proposing or requiring an LCA for each individual product on the SKU level (in different dosages and/or pack sizes) is neither feasible nor economically viable. The scale of such a requirement would impose **a significant administrative burden** on companies and divert essential resources away from implementing tangible decarbonisation measures across their operations.

The estimated cost of conducting a single LCA can range from **€50,000 to €200,000**, depending on the complexity and data availability. When multiplied across a company's full product portfolio (hundreds to thousands of products, and even tens of thousands of SKUs), **the financial burden becomes unsustainable**, especially in a sector characterised by narrow profit margins. Crucially, these costs do not yield proportionate environmental benefits. On the contrary, they risk triggering serious unintended consequences, such as an increase in medicine prices, potential market withdrawal of essential, low-cost medicines, and a greater risk of supply disruptions and shortages.

Moreover, LCA requires specialised technical expertise and robust methodological know-how. Most generic medicine manufacturers, **particularly small and medium-sized enterprises**, do not have the in-house capacity to perform such assessments. Engaging external consultants or investing in training and systems adds further financial strain and will require time. As LCA methodologies continue to evolve, maintaining compliance would necessitate ongoing investments in knowledge, tools, and staff, compounding the long-term operational burden.

In this context, allocating resources to broad, manufacturing-site or company-level environmental strategies offers a far more effective and impactful path toward emissions reduction than costly, fragmented product-level assessments, a point we will revisit in the sections that follow.

Distorted Sustainability Efforts

Prioritising product-level LCAs risks distorting sustainability efforts across the generic pharmaceutical sector. While well-intentioned, this approach could unintentionally incentivise companies to focus on a narrow subset of medicines, typically those with simpler supply chains or more visible emissions profiles, where environmental data is more readily obtainable. This may lead companies to allocate resources toward optimising a limited number of products, while deprioritising system-level changes that could yield far greater environmental benefits across their full operations. As an unintended consequence, the product-level LCA approach could lead to selective prioritisation of certain medicines, potentially limiting access to a wider range of treatments. This fragmented focus ultimately favours short-term, surface-level improvements at the expense of sustained, company-wide decarbonisation, substituting genuine progress with performative compliance.

A more balanced and transparent approach is essential to developing a standard that is both fit for purpose and broadly supported. For the off-patent sector, site-level or company-wide decarbonisation strategies represent a more effective and practical alternative to product-level LCAs. These approaches align more closely with operational realities and are likely to deliver greater environmental impact across the full breadth of generic medicine portfolios, as we will argue in the next section.

A viable alternative: risk-based environmental compliance at the company- or manufacturing site-level

The goal should be to reduce emissions meaningfully and support environmental sustainability, while also promoting and safeguarding access to affordable, essential medicines. One possible direction could be to explore a more targeted, risk-based approach to environmental improvement at the company or manufacturing site level. This kind of approach would allow efforts to be focused where they are likely to have the greatest impact, i.e. on higher-emission operations, rather than applying uniform requirements across all

products and sites. By aligning action with actual environmental risk, such a model may offer a more practical and effective path forward for the off-patent sector, balancing sustainability goals with the need for operational feasibility and supply resilience. To be effective and practical, such an approach should be designed to align with and complement existing EU environmental and regulatory frameworks, including Good Manufacturing Practices (GMP), the Waste Framework Directive, REACH, EU PPWR, and EU Taxonomy, ensuring consistency and avoiding duplication. By building on these established systems, we can avoid duplication and administrative overload while reinforcing regulatory coherence.

In parallel, broad **company-wide emissions reduction** strategies should be supported, alongside voluntary environmental reporting frameworks that are proportionate and tailored to the operational realities of the off-patent sector. Collaboration across the industry must also be encouraged to **share data**, best practices, and scalable solutions.

The off-patent industry stays committed to advancing sustainability, provided that regulatory approaches are practical and support continued access to affordable medicines. To be effective, national and local policies should align with globally recognised standards for greenhouse gas emissions assessments and for setting company-wide reduction targets, including through SBTi methodologies. Prioritising proven, system-level reporting frameworks over product-specific tools could help ensure consistency, feasibility, and environmental progress without compromising medicine availability.

Sustainable procurement of generics: environmental award criteria

Medicines for Europe advocates for the integration of sustainable **procurement principles into public procurement frameworks**. Recognising the limitations of traditional product-level LCA for off-patent medicines, we propose a more appropriate and sector-sensitive methodology to assess sustainability. This alternative approach should:

- **Incentivise and recognise science-based greenhouse gas reduction targets,** approved and validated by the SBTi and public reporting in alignment with the GHG protocol – to promote real reduction efforts and access to relevant information.

- **Recognise company-wide sustainability commitments**, including long-term measures for greenhouse gas (GHG) reductions, energy efficiency, and responsible waste and water management, rather than limiting assessments to isolated product-level improvements.
- **Focus on widely established and recognised standards and certifications – such as ISO140001, Ecovadis, CDP-Climate, AMR manufacturing standard and others to ease the assessment by the procurers.**
- **Establish and align at EU level clear carbon reduction priorities** that allow companies to channel efforts and investments into the most impactful emission-reduction strategies. Alignment between different procurers is necessary to create a bigger impact and reduce the burden of different requirements in different countries.

Green Public Procurement (GPP) presents a valuable policy lever for encouraging environmental progress in the off-patent pharmaceutical sector. By incorporating **objective and measurable environmental criteria** in tendering processes, public authorities can support and reward companies that adopt **internationally recognised sustainability standards**, such as ISO 14001 for environmental management and the Science-Based Targets initiative (SBTi) for GHG reductions.

Generic manufacturers are already making significant investments to improve environmental performance across production facilities and supply chains. These include participation in cross-industry initiatives such as the **AMR Industry Alliance's Common Antibiotic Manufacturing Standards and the Responsible Effluent Management Principles**, as well as widespread efforts to **transition to low-carbon and renewable energy** sources across **manufacturing and R&D operations**.

However, to meet the EU's climate-neutrality objective by 2050 and ensure the resilience of the generic medicines supply chain, further policy action is needed. **GPP can play a role by providing meaningful incentives to companies adopting sustainable practices, while ensuring continued access to affordable medicines.** At present, however, recognition of industry-led environmental efforts in procurement processes remains inconsistent and often lacks alignment with established, measurable industry standards. While the European Commission has developed tools to support the inclusion of environmental requirements in public procurement, **no specific guidance currently exists** for pharmaceuticals.

To address this, we propose a **pragmatic and proportionate framework** that enables the inclusion and harmonisation of environmental criteria in tenders without creating unnecessary administrative or financial burdens. We recognise that public procurers may not always have the technical capacity to assess the sustainability of pharmaceutical manufacturing in detail. Therefore, we recommend that **procurement processes rely on existing, verifiable, established standards, certifications (e.g. ISO), and publicly available data platforms (incl. ESG company ratings)**. Specifically, we support the inclusion of standardised environmental award criteria that reward adherence to **independently recognised benchmarks** and self-regulatory best practices. These include responsible wastewater management, GHG reduction strategies, and broader supply chain sustainability commitments.

Furthermore, it is critical that environmental criteria in procurement acknowledge **the long-term nature of transformational climate action**. Reaching net-zero emissions will require significant and sustained effort. As such, tenders should not only reward current performance but **also recognise forward-looking strategies** and publicly declared commitments that reflect credible, near-term progress toward decarbonisation and broader environmental improvements.

In addition, assessing large, diverse product portfolios individually risks creating excessive administrative complexity. This approach may conflict with the EU Compass objectives on simplification and harmonisation and could potentially drive manufacturing away from Europe toward regions offering more predictable and science-based regulatory frameworks.

Antimicrobial resistance

In the specific case of antibiotics, the industry has made significant efforts to limit the development of antimicrobial resistance and is committed to continuing to invest in practices protecting the continued effectiveness of antibiotics as well as their availability to healthcare professionals and patients. **The AMR Industry Alliance has established a manufacturing standard**, which provides **clear guidance** to manufacturers in the global antibiotic supply chain to ensure that their antibiotics are made responsibly, helping to minimise the risk of AMR in the environment.

As such, the Standard requires that the manufacturer of an antibiotic must have an effective environmental management system and that the antibiotic's Predicted No-Effect Concentrations (PNEC), or the level at which a substance will not have an adverse effect on its environment, are met. To provide further guidance and quality assurance, **a certification scheme has been developed**, which enables antibiotic manufacturers to demonstrate, through **independent third-party evaluation, that the requirements of the Standard have been satisfied.**

MEAT (Most Economically Advantageous Tender) criteria related to sustainability should focus on carbon reduction, responsible waste and water management, AMR mitigation, and recognised standards such as ISO 14001 and SBTi.

Conclusion

The generic medicines industry is taking **concrete steps to reduce its environmental footprint**, with a strong focus on company-level GHG reduction targets to help drive down emissions **across the pharmaceutical supply chain**. This company-level approach drives broad, systemic change across the off-patent pharmaceutical sector and is more impactful than product-level LCAs.

The language around product-level LCAs must therefore make it explicitly clear that these assessments are **not intended for use in regulatory or procurement processes** to select or prioritise medicines. LCAs are tools to support developers in improving processes during the development and manufacturing of medicines, not for determining which products should or should not be used.

We advocate for the adoption of **comprehensive, company-wide strategies** that prioritise sustainable practices and align **with sector-wide environmental benchmarks**. This approach enables the generic medicines industry to contribute meaningfully to the EU's climate neutrality objectives while preserving access to affordable medicines, a cornerstone of public health policy.

We call on policymakers to incorporate **measurable, realistic environmental standards into Green Public Procurement and healthcare procurement frameworks** that reflect the specific characteristics of the off-patent sector. Doing so will ensure continued progress on sustainability without undermining the resilience, affordability, and availability of essential medicines in Europe.

Medicines for Europe
Rue d'Arlon 50 - 1000 Brussels - Belgium
T: +32 (0)2 736 84 11 - F: +32 (0)2 736 74 38
info@medicinesforeurope.com
www.medicinesforeurope.com