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ABSTRACT

A COLLABORATIVE APPROACH TO DEVELOP PRODUCT CATEGORY RULES (PCR) FOR PHARMACEUTICAL PRODUCTS

A growing and ageing world population, together with impacts resulting from a rapidly changing climate, has come hand in hand with a parallel surge in demand for pharmaceutical products and healthcare interventions. Simultaneously, the pharmaceutical industry is increasingly expected by both regulators and buyers to deliver and guarantee access to high-quality medicine, while reducing the environmental impacts associated with the production, distribution, use and end-of-life of pharmaceuticals.

Life Cycle Assessment (LCA) provides an effective tool to assess and compare the environmental impacts of pharmaceuticals and to execute environmentally optimised drug designs and manufacturing. However, the high degree of methodological flexibility possible under the International Organization for Standardisation (ISO) 14040/14044 standards has so far led to inconsistent and incomparable results, for example due to methodological choices on the functional unit (FU), system boundaries, and cut-off criteria.

This, in turn, reduces robustness, reproducibility, and accuracy of comparisons between different medicines and pharmaceutical products. As a result, a standardised framework and harmonized rules on how to perform LCAs in the pharmaceutical sector are needed to guide practitioners towards more robust, science-based, reproducible, and comparable LCAs.

Recognising the importance of a harmonised method to measure and report the environmental impact of medicines and healthcare products, the Sustainable Markets Initiative (SMI) Heath Systems Task Force has worked with the Pharmaceutical Environment Group (PEG) through a newly created consortium and NHS England to support the development of a sector-wide standard for medicines LCA.

The Pharma Life Cycle Assessment (LCA) Consortium and NHS England intend to work with the British Standards Institution (BSI) to reach consensus among the sector's stakeholder groups including healthcare systems, providers and professionals, representative bodies, academics and patients to establish the standard. This will improve transparency and support the assessment and reduction of the environmental impact of medicines across their manufacture, supply, use and end of product life.

PEG

Sustainable Markets Initiative

BACKGROUND

The SMI Health Systems Task Force has been formed to take joint, scalable action to accelerate the delivery of net zero healthcare – to improve individual, societal, and planetary health – and to collectively address emissions across supply chains, patient care pathways, and clinical trials. With relevance to patient care pathways, the Task Force has publicly committed to:

- **Engage and collaborate** with health policy makers, regulators, payers and providers, and hospitals from across the globe to raise awareness of the need and the opportunity to decarbonise care pathways.
- **Build an end-to-end care pathway emissions calculation standard and tool** for specific diseases that allows stakeholders to **measure and track emissions** across the care pathway and assess decarbonisation strategies.
- **Align on a common framework to perform LCAs** with private sector members also committed to publishing product-level LCA data across their product portfolio to increase transparency on treatment emissions.

The Pharmaceutical LCA Consortium was formed in response to the third commitment, a collaboration of eight global pharmaceutical companies – AstraZeneca, GSK, Johnson & Johnson, Novo Nordisk, Pfizer, Roche, Sanofi, and Takeda – formally launched on 1st November 2023. Its purpose is to facilitate a universal approach to assessing the environmental impact of pharmaceutical products, the outcomes of which can be judged equally and used to make informed choices about product development and patient care.

As the first healthcare system to commit to reaching net zero emissions, the NHS in England is also working to tackle emissions related to the medicines it purchases, prescribes, dispenses and disposes of. This is why the NHS is collaborating with the consortium to co-sponsor the development of a standard to codify this methodology and to support the access, transparency, and consistency of the requirements. The standard development process will be led by BSI, an internationally recognized global expert in the development of consensus-led standards.

Ultimately the success of this work will be judged by the uptake and wide scale adoption of the standard by pharmaceutical companies around the world, regardless of company size, market or products supplier – from innovative drug manufacturing to generics manufacturers and over-the-counter medicines.

There are huge benefits for patients, healthcare providers, the sector, and stakeholders from developing a shared way of measuring and reporting a product's potential environmental impact. To achieve this requires a partnership effort by the 'healthcare system', with all actors willing to play their part.

This collaborative programme is broad and complex, seeking to create both an approach and a standard that can be used by healthcare stakeholders around the world. This abstract outlines the aims and objectives of the standard more broadly, then focuses on the initial work of the consortium to align amongst manufacturers on a technical approach to a common methodology that will inform the consortium's input into the development of the standard. More information on the consensus building process and standardization process will follow in due course.

AIMS AND OBJECTIVES

Working closely with industry experts from participating companies, healthcare systems, and other relevant stakeholders, the aim is to develop an LCA standard aligned to relevant global standards, for measuring, reporting, and communicating product-level environmental footprint data for the pharmaceutical sector by the end of 2025.

Specifically, the project aims to:

- Develop PCR(s) for pharmaceutical products through a standard that define a set of guidelines for conducting LCAs that enable the measurement and reporting of environmental information at a product level. The PCR(s) must be relevant and applicable across the entire range of pharmaceutical products, and flexible enough to accommodate for different product categories, regardless of geography. Our ambition is that the methodology will form the definitive way to assess environmental impacts of products across the entire pharmaceutical sector.
- Engage key stakeholders from the pharmaceutical and broader healthcare ecosystem through the formal BSI Standard Steering Group to ensure the standard is representative of the views of the whole sector and fit for purpose, and to drive adoption.
- Produce a set of documents that describe the PCR and their application for pharmaceutical products in a way that is straightforward to understand, articulate, and communicate to help the support wide adoption on the standard developed.

> **OUR AMBITION IS THAT THE METHODOLOGY WILL FORM THE DEFINITIVE WAY TO ASSESS ENVIRONMENTAL IMPACTS OF PRODUCTS ACROSS THE ENTIRE PHARMACEUTICAL SECTOR**

WHAT ARE PRODUCT CATEGORY RULES?

Performing an LCA is no simple undertaking for any product, but is particularly challenging given the typical complexity of pharmaceutical products. An LCA requires many choices to be made regarding sources of data, the boundaries of the system, allocation of impacts, and the choice of metrics used to estimate them, among others.

The number of choices can make the comparability, and therefore the utility of the resulting data, hard to judge when evaluating different products. A PCR provides category-specific guidance for estimating and reporting product life cycle environmental impacts.

PCRs have been developed by some other sectors in a holistic and complete way – including apparel and footwear, beverages, and electronics – but not for pharmaceutical products. However, it is recognised that increased consistency of product-level information is a key driver in term of reducing the environmental impact of healthcare – enabling providers, medical professionals, and even patients to make informed choices about the products or care provision they choose.

UNDERSTANDING THE PCR LANDSCAPE

The first step in the development of this PCR is to understand and learn from others, both in terms of available academic literature, other sectors' experience, and the approaches already utilised across the industry.

Many pharmaceutical companies have been working in this area for several years and have undertaken many LCAs on their products, but only a few are in the public domain. Harnessing this knowledge and sharing experiences for the first time as part of a sector-wide initiative has been a vital and valuable starting point.

The literature review ranged from general guidelines on footprinting and PCR development, relevant international standards (such as those developed by ISO and the GHG Protocol), pharmaceutical and chemical sector specific guidelines, existing PCRs, and tools for chemical product synthesis and footprint modelling.

The review showed that the PEF (Product Environmental Footprint) method developed by the European Commission[1] provides a strong foundation for PCR development, as well as methodological guidance for conducting LCAs. In December 2021, the Commission adopted a revised Recommendation on the use of Environmental Footprint methods, helping companies to calculate their environmental performance based on reliable, verifiable, and comparable information. This established one of the world's first common frameworks for undertaking an LCA. This comprehensive framework will form an important basis for the methodological guidance of this PCR. Also of particular relevance is the PCR for global pharmaceutical products drafted by the Technical University of Berlin[2] and Pharmaceutical and Medical Device Carbon Footprinting Standard developed by the Sustainable Healthcare Coalition[3].

When considering the practice of the consortium members, there is convergence towards similar methodologies in line with progress observed in the field of LCA. This will help to align on several aspects of the methodology, such as the preferred methodological framework as well as the definition of a pharmaceutical product for the scope of the PCR, functional unit and system boundaries.

[1] PEF method refers to the Commission Recommendation of 16.12.2021 on the use of the Environmental Footprint methods to measure and communicate the life cycle environmental performance of products and organisations - Annex 1

[2] Siegert, M.-W., Finkbeiner, M., Emara,Y., Lehmann, A. (2019). Product Category Rules (PCR) for pharmaceutical products and processes. Technical University of Berlin. https://doi.org/10.14279/depositonce-9143

[3] https://shcoalition.org/pharmaceutical-and-medical-device-carbon-footprinting-standard/

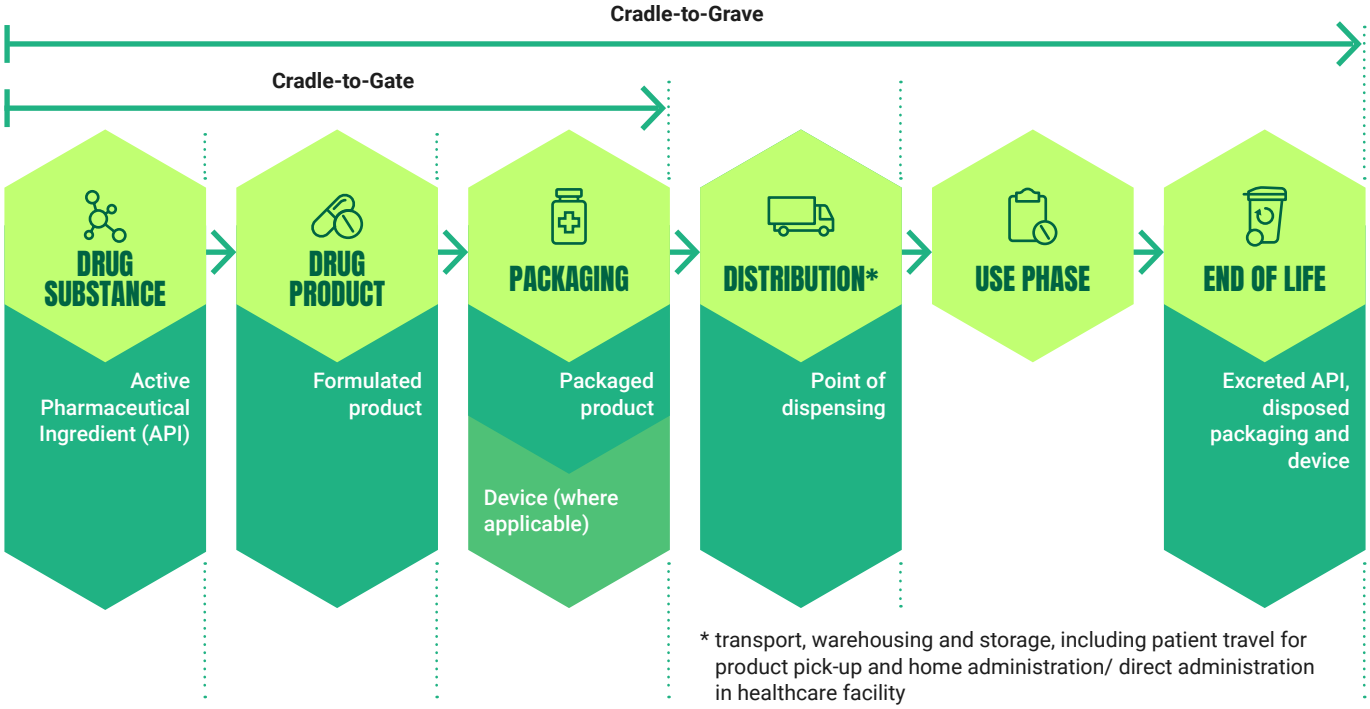
SCOPE AND DEFINITION - INITIAL PREPARATORY WORK FROM THE CONSORTIUM

In advance of the standard process beginning, the consortium members have embarked on efforts to align on their view of the scope and definition for the standard. The following outlines the views of the scope by consortium, with the intention of bringing to the standard development process for discussion, consultation and consensus with other stakeholders. Due to the diversity of drug substance modalities and drug product formulations to be covered by such PCRs, agreed-upon criteria will be defined. Where deemed useful, more detailed rules and modelling assumptions will be set for product sub-categories.

Functional Units (FU) will be determined to meet varying stakeholder needs, and relevant life cycle stages and processes, as well as impact categories, will be identified. Respective data requirements will be set, and inventory modelling support will be provided.

The consortium view is that the scope of the PCR is intended to cover any pharmaceutical product and, within the context of the early stages of this work, this has initially been defined as: *"Any product that includes any substance or combination of substances, presented as having properties for treating or preventing disease in human beings, which may be used in / administered to human beings either with a view to restoring, correcting or modifying physiological functions, by exerting a pharmacological, immunological or metabolic action"*. This definition is largely inspired by the European Commission definition in Directive 2001/83/EC[4], with some adaptations.

The PCR aims to cover the cradle-to-grave life cycle impacts of pharmaceutical products. This essentially sets the boundaries for which processes and stages of a product's life cycle need to be considered. The initial framing seeks to utilise six product life cycle stages, set out below:



* transport, warehousing and storage, including patient travel for product pick-up and home administration/ direct administration in healthcare facility

[4] Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. Official Journal L 311. 28 November 2001. pp. 67–128 https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:en:PDF

The PCR will seek to cover a range of environmental impacts, not just those relating to GHG emissions. We recognise the need for a holistic view of environmental impact, particularly as the interdependencies between different impacts comes into sharper focus as the effects of Climate Change become more apparent.

The FU used for an LCA provides the quantified description of the performance of a product type. It is a normalising factor, which is important as it establishes the way that environmental impacts can be compared on a like-for-like basis. In the initial work from the consortium, the FU for a pharmaceutical product has been initially determined to be: *"Treatment of one child or adult with [disease/indication] for [period of application] or prevention of [disease] in one child or adult for [period of protection]"*. This is similar to the functional unit considered in the draft PCR guidance published by the Technical University of Berlin.

The PCR is likely to use scenarios to cover the wide variety of pharmaceutical products and types (from innovative drug development to generic medicines). For each scenario, modelling rules for processes in a life cycle stage will be developed, with particular focus on those expected to have a significant impact on the results. They will be designed during the PCR development process and will – in the absence of good quality primary data – describe the appropriate use of secondary data, proxies and assumptions.

WE RECOGNISE THE NEED FOR A HOLISTIC VIEW OF ENVIRONMENTAL IMPACT, PARTICULARLY AS THE INTERDEPENDENCIES BETWEEN DIFFERENT IMPACTS COMES INTO SHARPER FOCUS AS THE EFFECTS OF CLIMATE CHANGE BECOME MORE APPARENT

As part of the standard development process, pilot studies will be conducted to test the PCR and the input received during this process will be incorporated into a revised version that will be opened to external stakeholder consultation. This consultation will seek to ensure that a wide range of views are accounted for during the PCR development process to promote its uptake and acceptance when launched.
This consensus-led consultation process will be run an accordance with BSI's internationally recognised standard development process.

The PCR will also act as a foundation for other activities, including improvement of the product inventory data used to undertake LCAs and create an accessible tool that facilitates the ease with which they are undertaken.

This abstract describes the initial steps in an overarching programme to improve the measurement and reporting of environmental information for medicines. The technical work described is a key foundational element that will lead to the development of a universal, consensus-led standard for the benefit of the global healthcare systems, in its many forms, and ultimately for the improved health of patients and the environment in which they live.