

CRITICAL REVIEW STATEMENT

LIFE CYCLE ASSESSMENT OF PATIENT INFORMATION LEAFLETS

BACKGROUND

The life cycle assessment (LCA) study 'Life Cycle Assessment of Patient Information Leaflets' was undertaken by LCA practitioners from the consultancy Long Trail Sustainability (LTS) on behalf of Takeda. The goal of the study was to conduct an attributional, life cycle assessment (LCA) comparing the environmental performance of an average paper patient information leaflet (PIL) against an alternative digital version, an electronic patient information (ePI) document, as viewed on a smartphone. The study was undertaken for the European market.

The audience for the study includes the following:

- Takeda and other members of the European Federation of Pharmaceutical Industries and Associations (EFPIA), which represents innovative pharmaceutical companies present in the European market; and
- Customers of drug products (e.g. healthcare providers), patients/consumers, and other external stakeholders.

The intended use of the study is to:

- Inform EFPIA members on the environmental costs and benefits associated with moving to ePI from paper PIL; and to
- Communicate these findings to external stakeholders.

CRITICAL REVIEW PROCESS

The study was critically reviewed by a panel of three independent experts:

- Dr Peter Shonfield, ERM (panel chair);
- Dr Matt Fishwick, Fishwick Environmental; and
- Dr Matteo Cossutta, Aria Sustainability.

The reviewers are independent of any party with a commercial or any other interest in the study.

The aims of the critical review process were to ensure that:

- The methods used are consistent with ISO 14040 and ISO 14044;
- The methods used are scientifically and technically valid;
- The data used are appropriate and reasonable in relation to the goal of the study;
- The interpretations reflect the limitations identified and the goal of the study; and
- The study report is transparent and consistent.

The critical review process involved the following:

- Review of the initial LCA study report prepared by EFPIA members titled "Life-Cycle Assessment of E-leaflet vs Paper leaflet" dated 15 January 2024.
- Following feedback on the initial report Takeda engaged LTS to update the study. Two versions of the draft Goal and Scope Definition document (10 January 2025 and 6 February 2025) and two draft versions of the LCA Study Report (1 April 2025 and 14 May 2025) were reviewed by the panel according to the criteria listed above and recommendations for improvement were provided to LTS, who then provided their responses.
- A review of the third and final version of the report (29 May 2025), in which the authors of the study addressed all the reviewers' comments.

The critical review did not involve a review of the LCA models developed by LTS, so all the findings of the critical review are based solely on the LCA study report provided to the review panel during the review process.

CONCLUSION OF THE CRITICAL REVIEW

The reviewers confirm that this LCA study follows the guidance of, and is consistent with, the international standards for life cycle assessment (ISO 14040:2006 and ISO 14044:2006) as follows:

- The methods used are scientifically and technically valid given the goal of the study;
- The data used are appropriate and reasonable in relation to the goal of the study;
- The interpretation of the results and the conclusions of the study reflect the goal and findings of the study; and
- The study report is transparent and consistent.

This critical review statement is only valid for the final LCA study report as presented to the reviewers, dated 29 May 2025.



Dr Peter Shonfield



Dr Matt Fishwick



Dr Matteo Cossutta

02 June 2025