THINK TANK WORKSHOP REPORT

Integrating pharmaceutical pollution into healthcare decision-making through Life Cycle Assessments (LCAs)

Wednesday 27th September 2023

Background

When seeking to reduce the environmental impacts of pharmaceuticals used in UK healthcare, one of the key leverage points for change is integrating environmental footprint criteria into healthcare decision-making strategies. Currently, decisions on which pharmaceuticals to licence, approve, procure, prescribe and dispense, are almost entirely based upon clinical outcomes and economic cost.

Life cycle assessment (LCA) is an economic modelling tool being applied in efforts to integrate the environmental footprint of medicines into healthcare decision-making processes. A full LCA considers the carbon footprint accumulated throughout the life of a pharmaceutical, from the extraction of raw materials and its manufacture, through to its use in healthcare, disposal/excretion by patients, and its eventual impacts on the environment.

LCA data is important in supporting systems-level change. It enables us to identify the stages of the life cycle where there are greatest environmental risks, and work together to mitigate these. It also allows us to compare the environmental impacts of two different pharmaceuticals, or two different methods of manufacturing, administration, disposal, etc, to environmentally-optimise our pharmaceutical supply chains and practices. Importantly, it facilitates informed sustainability decision-making processes, to consider all three sustainability pillars: the environment, economy and human health. A sustainable medicine must work across all three.

The environmental impacts of pharmaceutical usage in healthcare are substantial and go far beyond carbon, to include pollution, freshwater usage (pharmaceutical manufacturing is a highly water-intensive process), raw material extraction, change in land usage, etc. We therefore need to develop LCA tools to integrate these wider impacts alongside carbon.

In September 2023, the Pharma Pollution Hub brought together a group of around 30 thought leaders from across the pharmaceutical, healthcare and environmental sectors, to discuss the issue of integrating pharmaceutical pollution into LCAs. In this report, we outline the key challenges identified, and opportunities we believe could accelerate action in this field.

Addressing data gaps

The lack of data is undoubtedly a major barrier in integrating pharmaceutical pollution into LCAs: we use approximately 2000 active pharmaceutical ingredients (APIs; the biologically active component of a medicine) in healthcare, but we only have comprehensive environmental toxicity data for around 12-15% of these. This is because around 85% of the medicines used in healthcare are generics that were licensed before the 2006 introduction of European Medicines Association guidelines stipulating the need to provide environmental risk assessment data for the registration of new human medicines. This means that we don't know the environmental effects of most of the medicines we are using.

We also don't know enough about what happens to APIs once they are excreted from our bodies – how much ends up in the environment following wastewater treatment, where in the environment they

accumulate (e.g. do they remain in the water or accumulate in the sediment or within wildlife), how long do they remain active in the environment before they are broken down, how toxic are their breakdown products, how are their biological activities altered by other compounds also present in the environment… The list of environmental data gaps is long, and this is accompanied by a long list of upstream data gaps – how much pharmaceutical pollution enters the environment throughout the very complex and global manufacturing supply chain networks (there can be up to a thousand different chain links for a single pharmaceutical), how much is wasted throughout the healthcare process through expiry, how much is actually consumed (and where), how much is inappropriately disposed of (and where)…

In terms of the environmental data gaps, large-scale initiatives are already addressing many of these questions and uncertainties, through two European Union-funded initiatives the PREMIER and TransPharm projects. The PREMIER project is developing predictive models, databases and assessment tools to support greener drug design and the prioritisation of pharmaceuticals to target for both environmental risk data collection and upstream interventions to mitigate environmental impacts. Similarly, the TransPharm project is also focused on greener design and manufacture, including how to make these processes financially viable for pharmaceutical investment. TransPharm is also working to integrate environmental data into sustainability assessments (such as LCAs).

There is recognition of the need for standardised criteria for what constitutes a "sustainable pharmaceutical", to support eco-design, sustainable investment and healthcare decision-making, and this is being addressed by the British Standards Institution (BSI), who are working across stakeholder groups to develop this. Pharmaceuticals in the environment has been identified as one of several priority environmental categories for this initiative.

Despite the scale of the challenge, there was consensus amongst workshop participants that we must not use incomplete datasets as an excuse to delay action. The following needs were identified in order to accelerate progress on data availability and access:

- **Identify and harmonise available datasets from across the whole life cycle**. Currently data is collected from a range of different databases, academic literature and company websites, with varying levels of quality, reliability and relevance. Many of the environmental impacts of pharmaceuticals are likely to be from their use and disposal; these data are currently not systematically measured, and therefore we need to identify who is responsible for their collection and management, what data are already available, and what challenges there may be in collecting them (e.g. ethical and practical implications of collecting data from patients).
- **Collect more case studies of full LCAs for pharmaceutical pollution.** There are currently very few case studies available that have attempted to conduct an LCA across the entire pharmaceutical life cycle (also known as "cradle to grave"). Without this, we cannot identify the critical areas requiring methodological research and development.
- **Greater focus on gathering data for generic medicines.** We need to develop better mechanisms to make LCA data from generic manufacturers available.
- **Use existing frameworks to standardise methodologies and data sharing.** There are a number of initiatives creating evidence-based targets to standardise corporate sustainability strategies and approaches, for example the Science-Based Targets Initiative, the Sustainable Markets Initiative, the Taskforce on Nature-related Financial Disclosures. Currently, pharmaceutical pollution targets are not consistent or comprehensively addressed within these, so there is a need to develop clear targets/standards and integrate these into existing frameworks; this will hopefully be streamlined through the BSI initiative.
- **Harmonise data collection across stakeholders and countries.** Given the amount of data required for LCAs, countries and sectors need to be consistent in what data they demand from the pharmaceutical industry. Therefore, regulators and healthcare sectors from the main pharmaceutical markets (in

particular those from across the UK and EU) need to work together to harmonise and standardise data needs; this will also be aided through the creation of standards and targets.

Uptake into the healthcare system

Pharmaceutical pollution could be integrated into decision-making at a number of different points within the healthcare system, each of which involves different stakeholder groups who use data in different ways. Identifying and clarifying how the LCA data will be used, and by whom, is therefore essential for focusing and optimising data collection and availability, in order to maximise and expedite action.

The One Health Breakthrough Partnership is a multistakeholder group that has been pioneering research on how to integrate pharmaceutical pollution into the Scottish healthcare system; their work has identified four potential decision-making points: at the policy level, at the health technology assessment stage, at formulary prescribing guidance, and at the patient/public level. The newest established Department of Health Economics and Environmental Sustainability at the York Health Economics Consortium has also been leading efforts to integrate sustainability into healthcare LCAs.

Workshop participants identified the following needs for improving the uptake of LCA outputs into healthcare decision-making:

- **Understand and work with the different stakeholder groups at each decision-making point.** We need to identify who are the stakeholders at the different decision-making points, and collectively create a strategy for integrating the LCA output data into their decision-making processes. This will need to account for dealing with trade-offs between multiple environmental sustainability criteria (e.g. carbon, pollution, water usage, etc). We need research and implementation strategies to understand and overcome the social and cultural barriers, as well as identifying which information is needed and in what format.
- **Minimise operational and ethical challenges by focusing efforts upstream.** For cohesive, effective integration, environmental criteria need to be included across all decision-making points, in a joined up way. However, the further upstream this is focused (i.e. ideally at the policy, registration and health technology assessment stages), the more this would minimise the operational and ethical challenges. For example, we need to minimise additional burden placed on prescribers, and avoid placing treatment decisions on patients who may have little control over their need for the treatment. Health Technology Assessment agencies already provide guidance, decision aids and implementation support for technologies, so are much better placed than prescribers and patients.
- **Expand healthcare policy scope to include international costs.** Current UK healthcare decision-making policies that consider the cost-benefits that are relevant to the UK population, whereas many of the environmental impacts occur outside this scope.
- **Improve our understanding of, and account for, the wider economic and human health/social costs of pharmaceutical pollution.** Currently, healthcare cost-benefit analyses only consider the direct economic costs and human health benefits of a medicine, and not the wider costs to society (e.g. the costs associated with preventing or managing pollution and/or the wider impacts of environmental degradation, biodiversity loss, contribution to antimicrobial resistance, etc). Identifying and using this evidence base will also help to better evaluate and communicate the benefits of non-pharmaceutical treatments, early diagnosis and preventative healthcare.

Galvanising public support

Within western societies, pharmaceuticals have become known as life-saving medicines and highly lucrative goods that our economy, modern lifestyles and healthcare systems rely upon. This means that there are

social, financial and ethical implications as we begin to acknowledge and take responsibility for their impacts as pollutants.

The public are arguably the most important and influential stakeholders in driving action: they are the pharmaceutical consumers, healthcare patients, taxpayers, industry shareholders, political voters and media readers; they are also the staff who work in the pharmaceutical, healthcare and environmental sectors.

Therefore, long-term, successful integration of pharmaceutical pollution into healthcare decision-making processes will only be possible with public support, in the context of a fair and just system that supports and encourages the need for action. To enable this, workshop participants identified the following needs:

- **Greater public awareness about the environmental impacts of pharmaceuticals.** Any efforts to integrate environmental criteria will likely have some form of trade-off in terms of economic or human health benefits, and therefore as a society we need to accept the need and responsibility for doing this.
- **Research into the ethical and social implications of public awareness campaigns.** There are likely to be health and economic trade-offs that may impact on some communities or demographics more than others (e.g. pharmaceutical usage is typically greater in children and older adults, with higher levels in socially-deprived communities), so we need to ensure that awareness campaigns are fair and ethical.
- **Research into the most effective and appropriate messaging for public awareness campaigns.** We need consensus on what messages are the most appropriate to convey in public awareness campaigns, and what framing and communication routes for reaching different publics.
- **Incentivise transparency for providing pharmaceutical pollution information across the pharmaceutical and healthcare sectors.** How can we reward companies that provide transparency in their supply chains, e.g. from a consumer perspective through preferred supplier status or increased prescribing/dispensing, or from a licensing perspective, through faster licensing, increasing patent lives. Disclosing environmental footprints should be considered a responsible manufacturing practice, rather than something that confers reputational and financial risk.
- **Incentivise accountability for pharmaceutical pollution across the pharmaceutical and healthcare sectors.** Both sectors are currently very focused on leading efforts to address carbon emissions, which is much easier to quantify (e.g. compared to biodiversity) and straightforward to mitigate/manage (i.e. with solutions already developed and available).

Conclusion

Overall, the workshop highlighted the breadth of the data sources required for integrating pharmaceutical pollution into LCA, and the vital need to be clear about how LCA outputs are going to be used for change, to inform those collecting and preparing the inputs. It identified many challenges, but highlighted even more opportunities for future research, and importantly demonstrated the enthusiasm and appetite amongst stakeholders to work collaboratively and develop solutions.

Workshop details

The online workshop was held on 27th September 2023. It was hosted by the Pharma Pollution Hub (Kelly Thornber, Charles Tyler, George Kirkham and Kerri Hall), in collaboration with Rosalie Arendt and Lara Wöhler from the University of Twente.

Facilitators: Ross Brown and Caroline Farmer (both from the University of Exeter) and Lydia Niemi (University of the Highlands and Islands, One Health Breakthrough Partnership).

Speakers: Rosalie Arendt (University of Twente), Charles Tyler (Pharma Pollution Hub), Stewart Owen (AstraZeneca), Ad Ragas (Radboud University), Sharon Pfleger (One Health Breakthrough Partnership), Mel Pegg (York Health Economics Consortium).

Other participants: Caroline Moermond (National Institute for Public Health and the Environment, Netherlands), Chloe Smithers (Astra Zeneca), Georgie Sowman (Healthcare Ocean), Hannah Blitzer (Wildlife and Countryside Link), Heather Brown (Lancaster University), Helen Wilkinson (Environment Agency), John Redshaw (Scottish Environment Protection Agency), Julze Alejandre (Glasgow Caledonian University), Karin Helwig (Glasgow Caledonian University), Keith Moore (Sustainable Healthcare Coalition), Lora Fleming (University of Exeter), Matthew Taylor (York Health Economics Consortium), Matthew Wade (UK Health Security Agency), Nobuko Ichikawa, Paul Southall (Worcestershire Acute Hospitals NHS Trust), Rodrigo Vidaurre (Ecologic Institute), Rupert Payne (University of Exeter), Sinead Brophy (Swansea University), Wiebke Schmidt (Environment Agency)