Grant Agreement nº:	**101057668**
Project acronym:	**ETERNAL**
Project name:	**Boosting the reduction of the environmental impact of pharmaceutical products throughout their entire life cycle.**
Start Date/Duration:	1st September 2022 /48 Months
Title:	Output from Making Pharmaceuticals UK Workshop event 24/04/2024
Participant responsible:	**Britest, UKCEH**

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1 Introduction

This document provides a short summary of the output from an ETERNAL Industry engagement workshop conducted as part of the Making Pharmaceuticals UK Conference programme held at the Coventry Building Society Arena, Coventry, United Kingdom, on 23rd and 24th April 2024. Making Pharmaceuticals run concurrently across the two days of the Making Pharmaceuticals and Distributing Pharmaceuticals joint Exhibiiton evento which brings together over 100 exhibiting suppliers to the pharmaceuticals supply chain under one roof. Areas of visitor interest include:

- Contract Formulation, Manufacture & Filling
- Manufacturing & Processing

- Packaging – Primary & Secondary
- Labelling
- Water Purification & Water Treatment Systems
- Waste Management
- GMP & Environmental Hygiene
- Laboratory & Analytical Equipment
- Test Equipment, Analysis & Testing Services
- Regulatory Environment
- Market Research & Marketing
- Data Management

The workshop, entitled *"Protecting people, protecting the environment: Designing sustainable pharmaceutical lifecycles for the future European regulatory landscape"* consisted of short presentations introducing both the context and substance of proposed changes to EU legislation following the launch of the 2020 Pharmaceuticals Strategy for Europe, and some emerging results of collaborative research within ETERNAL.

Following the launch of its 2020 Pharmaceuticals Strategy for Europe, the European Commission (EC) adopted the first draft of a new directive and regulation in April 2023, opening it up to public consultation. The workshop reviewed the new environmental protections offered under the proposed legislation and the associated requirements placed upon pharmaceutical manufacturers to assess the environmental impact of the entire lifecycle of a product, from manufacturing, through use, to disposal, and highlighted work being carried out in the ETERNAL project to visualise the interconnected system of socio-economic activity of which a typical pharmaceutical lifecycle is comprised, and to locate and assess the impacts of this activity.

Against this backdrop, the second part of the workshop consisted of dialogue with the audience to capture views both positive and negative on the prospective legislative changes and how new tools for process and system design, and better understanding of the environmental fate and eco-toxicological effects of pharmaceuticals can help those seeking to build compliance into their businesses.

2 Workshop Output

The following perspectives of workshop participants from across the pharmaceuticals value chain were captured for use by the ETERNAL project to help inform and direct work to produce a roadmap for integrating new scientific knowledge into regulatory risk assessment to target mitigations, modifications, and regulatory risk assessment, ultimately towards a greener, more sustainable environment.

Making Pharmaceuticals 2024, Coventry, 24th April 2024

Outputs from ETERNAL/IChemE workshop, "Protecting people, protecting the environment: Designing sustainable pharmaceutical lifecycles for the future European regulatory landscape"

Facilitated by: John Henderson (Britest), Rob Peeling (Britest/IChemE), Sam Harrison (UK Centre for Ecology and Hydrology), Adrian La Porta (Bryden Wood, IChemE)

Some notable changes

- ...for the first time, a requirement to **assess the environmental impact of the entire lifecycle of a product**, from manufacturing, through use, to disposal (current focus is largely on use and disposal).
- European authorities can, for the first time, **refuse, suspend or vary an authorisation on the basis of environmental harm without sufficient risk mitigation measures.**
- **Post-authorisation requirements** - ERAs must be performed on products authorised prior to the current regulation...**within thirty months of the regulation coming into force.**
- **ERAs should be continuously updated** with new information that might affect the outcome of the assessments ... "without undue delay" (currently ERA only requred prior to market authorisation).

1. Define "the project" within your organization initiated by this change. What needs to happen?

Bringing sustainability into the organization

Getting the language and the messages right for each audience

Getting a set of meaningful and actionable metrics

Supporting "designed thinking" - offering people potential pathways rather than a bewlidering range of possibilities - and helping with the choices

2. What new tasks are there? What new skills will be needed?

Systematic science is fundamental to success	Establish understanding
Quantified effects	Address the lack of capcity to understand concepts and impacts
Requires societal education - at all levels	Communication - scientists & engineers don't think & talk like other people!
Linking communications piece to professional roles	Good new - the scientific method is applicable to solving the problem!

3. What constraints are you operating under? Where are your challenges?

Getting the weightings right on the criteria

Science based decision making is only part of the big decision making overall

Can't just think in financial terms - how do we capture the right values?

Lack of data e.g. environmental risks and fates, Occ health - expensive to obtain and subject to uncertainty

Conversely, once someone has data they hold onto it for advanatage - not shared

e.g. toxicity doesn't appear in discharge limits

Amounts are insuffiicent for mass balance approach - we will always be data sparse and data uncertain

Decision making cannot wait upon all the data - must embrace uncertainty

We don't need all data - we only need as much as is useful