Deliverable

D6.8 - Plan for Stakeholder Engagement – Second version (M18)

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TRANS PHARM

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Contributors	
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Guadalupe Vinado	Benkei	PMO	Approved	14/02/2024
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To request a change to this document, contact the Document Author.

CONFIGURATION MANAGEMENT

NATURE OF DELIVERABLE		
R	Document, report (excluding the periodic and final reports)	
DEC	Websites, patents filing, press & media actions, videos, etc.	X
DEM	Demonstrator, pilot, prototype, plan designs	

OTHER	Software, technical diagram, algorithms, models, etc.	
ETHICS	Deliverables related to ethics issues.	
DATA	Data sets, microdata, etc	
DMP	Data Management Plan	
SCURITY	Deliverables related to security issues	

DISSEMINATION LEVEL		
PU	Public, fully open, e.g., web (Deliverables flagged as public will be automatically published in CORDIS projects.)	**X**
SEN	Sensitive, limited under the conditions of the Grant Agreement	
Classified EU-R	EU RESTRICTED under the Commission Decision No2015/444	
Classified EU-C	CONFIDENTIAL under the Commission Decision No2015/444	
Classified EU-S	EU SECRET under the Commission Decision No2015/444	

ACRONYM/ABBREVIATIONS	
CA	Consortium Agreement (contractual document between members of the consortium)
DoA	Description of Action (technical annex to the Grant Agreement)
EC	European Commission
EU	European Union
FTP	Funding and Tenders Portal: https://ec.europa.eu/info/funding-tenders/opportunities/portal/screen/home
GA	Grant Agreement (contractual document between EC and beneficiaries)
IPR	Intellectual Property Rights
KO	Kick Off (meeting)
MC	Management Coordinator
MTA	Milestones Trend Analysis
PC	Project Coordinator
PMO	Project Management Office
TL	Task Leaders
WP	Work Package
WPL	Work Package Leaders

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Disclaimer

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1 EXECUTIVE SUMMARY

The research project *"TransPharm - Towards a sustainable pharmaceutical production"* is a four-year Research and Innovation Action (RIA) which has been accepted for funding with the European Union's Horizon Europe Framework Programme (HE/2021-2027), under Grant Agreement n°101057816.

This document presents the second version (due in M18) of the project's **Plan for Stakeholder Engagement**, first developed in Month 6 of the project and to be updated in Months 18, 30 and 42. This report represents the first update and has been finalised in Month 20.

2 DESCRIPTION OF THE DELIVERABLE OBJECTIVE AND CONTENT

The research project *"TransPharm - Towards a sustainable pharmaceutical production"* is a four-year Research and Innovation Action (RIA) which has been accepted for funding with the European Union's Horizon Europe Framework Programme (HE/2021-2027), under Grant Agreement n°101057816. This document presents the second, updated version of the project's **Plan for Stakeholder Engagement**. The first version was developed in Month 6 of the project; this version corresponds to the update due in Month 18. There will be further updates in Months 30 and 42.

Work Package 6's name – *"Stakeholder engagement, communication, dissemination, exploitation and training activities"* – provides already a summary of the work package's different areas of action. Table 1 presents an overview of the WP's tasks and their main objectives.

Table 1: Overview of WP6's tasks and their objectives.

Tasks	Main objective
Task 6.1: Plan for Stakeholder Engagement, Dissemination and Exploitation of Results	Development and update of planning for tasks 6.3 - 6.6.
Task 6.2: Data Management Plan	Development and update of project's Data Management Plan.
Task 6.3: Stakeholder engagement	Engaging with stakeholders (researchers, regulators, industry) to provide relevant inputs to WPs 2, 3 and 5 to increase relevance of task's outputs.
Task 6.4: Communication and dissemination	Sharing project news and outcomes with target groups.
Task 6.5: Exploitation management of project results	Facilitating exploitation of project results.
Task 6.6: Training activities	Developing training materials targeting industry / academia, healthcare actors, and potentially the broader public and water managers

This report (D6.8) presents the updated outcomes and planning for the stakeholder engagement to be performed within Task 6.3 and that of other stakeholder engagement actions within TransPharm. (A separate deliverable (D6.1) presents the planning for Tasks 6.4 to 6.6.)

TransPharm's **main goals** are:

- Help move towards a more sustainable European pharmaceutical production of Active
- Pharmaceutical Ingredients (APIs)
- To develop more sustainable and greener APIs that simultaneously reduce the environmental footprint and the dependence on third countries for API production.

- Deliver digital tools and guidelines, also based on artificial intelligence, for the development of greener pharmaceutical products and APIs, as well as models to judge their impact.
- Elaborate business cases for sustainable pharmaceutical products or APIs and what is needed to bring them to the market.
- Transfer key project results and knowledge towards targeted stakeholders.

TransPharm will achieve the following **breakthroughs**:

- The project will propose a multi-level approach to provide researchers and regulators with a better understanding of the environmental impact of pharmaceuticals. Tools and guidelines will be developed and shared with key stakeholders, so that the project's key results are widely known and adopted. These key results and knowledge will be transferred to targeted stakeholders: beyond researchers and regulators, as it is also of high importance that a wider community understands the environmental impact of pharmaceuticals.
- The project's objective is to generate scientific evidence related to the development, production, use and disposal of pharmaceuticals, so that public authorities can inform pharmaceutical strategies and policies based on scientific evidence.
- The project will contribute to the development and future use of greener pharmaceuticals by
  - (i) Creating a centre of excellence, with training actions dedicated to the young generation and researchers,
  - (ii) Provide scientific evidence that might help to the development of new standards,
  - (iii) Providing scientific evidence so that public authorities can inform pharmaceutical strategies and polices,
  - (iv) Empowering the healthcare sector and general public to a more sustainable use of pharmaceuticals, including sustainable procurement of pharmaceuticals.

It will assure **reliable access to key manufacturing capacity and will bring back production to Europe**. The EU will create an autonomous leadership position with on demand, faster, cheaper and more sustainable manufacturing of medicines products.

3 STAKEHOLDER ENGAGEMENT ACTIONS IN TRANSPHARM

Stakeholder engagement activities were planned as part of the following Work Packages and Tasks within TransPharm:

- **Work Package 4**, within *Task 4.1: A holistic framework for integrated sustainability assessment,* as part of *Task 4.1.2: Tailoring the assessment approach to stakeholder views, needs and wishes*
- **Work Package 5**, within *Task 5.1 Is there a business case for greener pharmaceuticals?*
- **Work Package 6**, within *Task 6.3: Stakeholder engagement*

The following sections provide an overview of the outcomes and planning of the different stakeholder engagement actions.

3.1 Stakeholder engagement within WP4 – Integrated sustainability assessment

TransPharm's WP4 kicked off with Task 4.1, which developed a holistic assessment framework for integrated sustainability assessments of pharmaceuticals. As part of this development process, T4.1 engaged with stakeholders to elicit their needs related to sustainability assessments of pharmaceuticals and how they will use assessments such as life-cycle analyses (LCAs).

The WP4 partner Ecologic planned and carried out an **interview campaign** to elicit stakeholders' views in relation to assessing the sustainability of pharmaceuticals. A questionnaire was developed jointly with WP4 partners, with particularly strong involvement of Radboud University and Ghent University. Key issues addressed in these interviews were: (1) stakeholder perception of the value chain and its resulting impacts, (2) what impact categories should be included, including dimensions not covered by traditional LCA (e.g., ecotoxicity, equity, working conditions), (4) how to weigh impacts against benefits, and (5) how stakeholders want to use the results.

Figure 3-1 presents an overview of the stakeholder affiliations of interviewees (total number of interviews = 21), based on a stakeholder typology developed for Task 4.1.

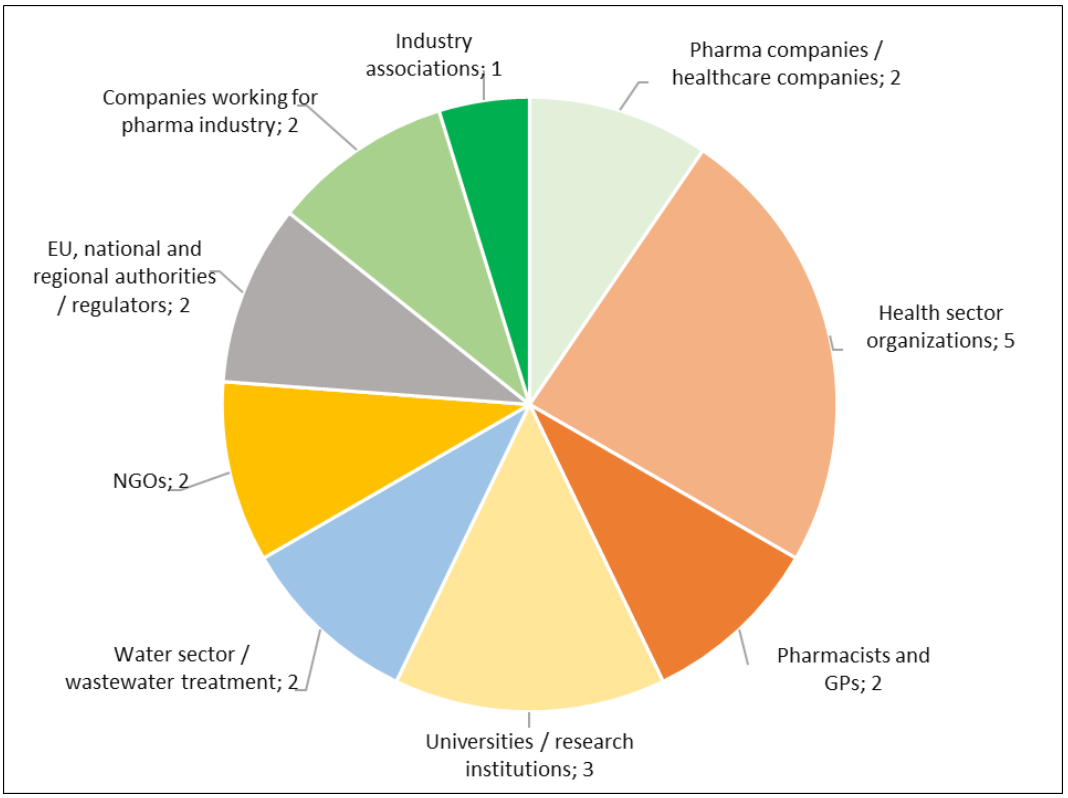

Figure 3-1: Overview of stakeholder affiliations of interviewees.
Numbers indicate number of interviews per group, total interviews = 21.

WP4 partners Radboud University, RIVM, Leuphana University and Ecologic also organised a joint **stakeholder workshop** with the IHI project PREMIER on 4-6 April in Nijmegen, the Netherlands. The workshop brought together a unique range of experts and professionals representing different stakeholders involved in the discovery, production, prescription, use and regulation of pharmaceuticals with around 100 participants. One of the interactive small group sessions was used to collect data for WP4, titled *Session 5. Sustainability assessment of pharmaceutical products – The need for a sustainability*. A short summary of the workshop outcomes can be accessed under this link.

The **outcomes of the stakeholder engagement activities within WP4**, including recommendations for developing an assessment system for the sustainability of pharmaceuticals, are presented in detail in the report TransPharm Deliverable D4.1 *"User requirements concerning sustainability assessments of pharmaceuticals".*

3.2 Stakeholder engagement within WP5 – Preparing for the transition to greener pharmaceuticals

Stakeholder engagement activities of Work Package 5's *Task 5.1 Is there a business case for greener pharmaceuticals?* were coordinated with those of Work Package 4. Section 5 of the interviews, discussed in the previous section, included three questions focusing on the barriers and

opportunities to the take-up of greener pharmaceuticals. Moreover, the above-mentioned joint stakeholder workshop between TransPharm and PREMIER included an interactive small group session to collect data for Task 5.1 titled: *Session 4. Criteria for greener production of pharmaceutical products – Is there a business case?*

Anonymised transcripts of the stakeholder interviews were provided to RIVM (lead partner of Task 5.1), and the responses to the three interview questions focusing on the business case are feeding into the further work of Task 5.1. Table 2 provides a summary overview of stakeholders' responses to the interview's Q18 on the barriers to uptake of greener pharmaceuticals.

Table 2: Summary of stakeholder responses on the topic of barriers to uptake of greener pharmaceuticals.

Barriers	Frequency
Costs	13
Legislation is not pushing for progress	9
Perception of having a less efficient API if it is more environmentally friendly	5
Lack of incentives	5
Lack of education	4
Lack of supply chain transparency	3
Big companies too slow to change/Lack of innovation	3
Lack of consummers pressure	2
Lack of definition	2
Change of drug master file and monograph too long/costly	2
Need to develop new production methods	2
Perception that if we put demands on the pharma industry, they will stop production	2

3.3 Stakeholder engagement within WP6 (supporting other WPs in the uptake of tools & methods)

To increase uptake of tools/methods developed in TransPharm, Task 6.3 implements a stakeholder-engagement strategy. The planned actions, to be started in M7, were:

1. interviews with key stakeholders (including Advisory Board members) will map expectations, requirements and use scenarios for TransPharm tools/methods.
2. online survey to reach a broader range of stakeholders, again mapping their needs and interest in particular features of TransPharm tools/methods.

The results are to be summarised in D6.3, in which the identified stakeholder requirements will be matched to an overview of the tools/methods, including a first specification of which requirements could be more easily incorporated in them and which are more challenging.

The engagement with WP leaders has shown as yet a relatively low "pull" for stakeholder engagement actions or clarity regarding their added value to the tools and methods being developed. Further discussions are taking place with WP leads to identify possible topics for stakeholder engagement, which are coordinated with interactions as part of *Task 6.5 Exploitation management of project results*.

The delays in the start of Task 6.3 mean that the submission date of *Deliverable 6.3: Report on stakeholder needs and interests related to TransPharm tools/methods* will need to be postponed from the originally planned Month 24.