Friday 10 July 2026	
9:15 – 9:45	Registration & coffee
10:00-10:15	Welcome remarks *W. Walentowska, Scientific Officer* and *MP. Costi, Action Chair*
10:15– 10:40	Action plan *A Cordeiro da Silva (University of Porto)* OneHealthdrugs overview *F. Piccolo (CA21111 manager)*
10:40 - 10:55	A Way Forward: Integrating Drug Research and Ecotoxicology *Eli Torè (University of Namur, (BE), Maria Paola Costi*
10:55 – 11:15	Coffee Break
11:15 – 12:30	***Round table "Scientific achievements and legacy"*** *Ulrike Wittig (HITS, Heidelberger) and Ioannis Papanastasiou (University of Athens), chairs* 15'Innovative therapy for vector-borne diseases can benefit the North and South: first, let's set the troubled scenarios Marcelo Molento , Universidade do Parana, Brazil 10'OneHealthdrugs From awareness to responsibility. European survey on Veterinary knowledge and attitudes towards environmental impact of pharmaceuticals. *Harry de Koning (University of Glasgow) and Clara Lima (University of Porto)* 10' Ecotoxicological data for real world medicinal products – change is needed? *Bruno Nunes (University of Aveiro)* 15'OHD:LUB project. OHD Drug–Target Interactions. A Predictive Platform for Future Drug Research *Crtomir Podlipnik (University of Ljubljana), Marko Jukic (University of Maribor) and Daniele Aiello (University of Modena and Reggio Emilia) (GDS, FAIRMol, OHD database)* 10'OHD Antiparasitic drugs pipeline *Guy Caljon (University of Antwerp) and Theodora Calogeropoulou (NHRF, Athens)* 5' Safety and sustainability in the drug discovery pipeline *Sandra Gemma (University of Siena)* 10' OneHealthdrugs programs for training and young researchers. The OHD model Sheraz Gul (Fraunofher, Hamburg) and Elisa Uliassi (University of Bologna)
12:30 – 13:30	Group photo and Lunch
13:30 – 14:00	*Pascal Marchand (University of Nantes) , Maria Laura Bolognesi (University of Bologna), chairs* Bridging COST Actions OHD and ENVIRANT Maria Valladares (University of Leon, ES) and Dimitros Karpoyzas (University of Thessaly, GR) Position paper from OneHealthdrugs MP Costi
14:00-14:45	**Success stories from Young Researchers and Innovators and OneHealthdrugs Ambassadors** Elisa Uliassi, Gulsah Bayraktar (Ege University, Turkey), Daniele Aiello (University of Modena and Reggio Emilia), Lori Doko (Università degli Studi eCampus), Eli Thorè (University of Namur), Kayhan Ilbeigi (University of Antwerp).
14:45-15:35	***Round table "Steps forward" with Industry and Regulators*** *Sheraz Gul moderator* SME role in the change. AI for a Safer Environment. Predicting and Mitigating Ecotoxicity of Pharmaceuticals G.A.I.A platform. Michail Papadourakis, Eleni Chontzopoulou - CloudPharm, Athens. Bruno Nunes, Paul Selzer (former Boehringer AH, University of Tübingen), Thomas Geurder (Zoetis), Pieter-Jan Serrany (Animal Health Europe).
15:35- 16:00	From Evidence to Action - Advancing the ASPECT Framework Beyond OneHealthDrugs: The Road to Policy Uptake and Long-Term Impact - Theo Zacharis, Greek Scientists Society M.P.Costi closing remarks

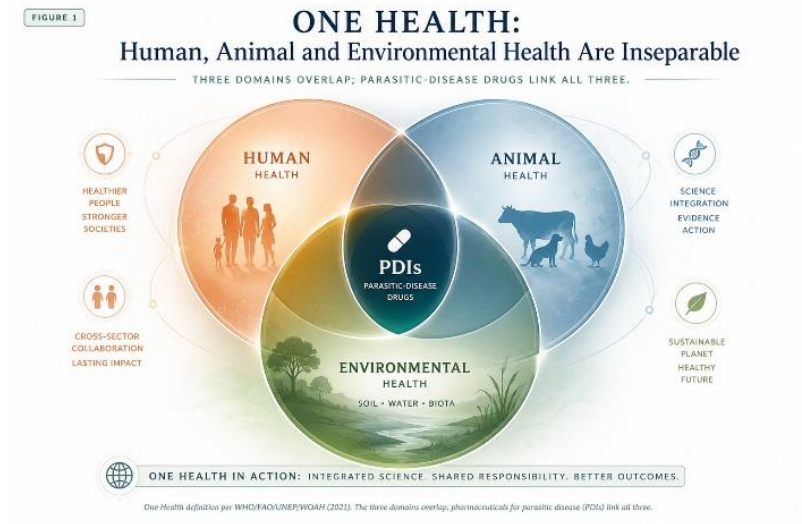
Conference Programme

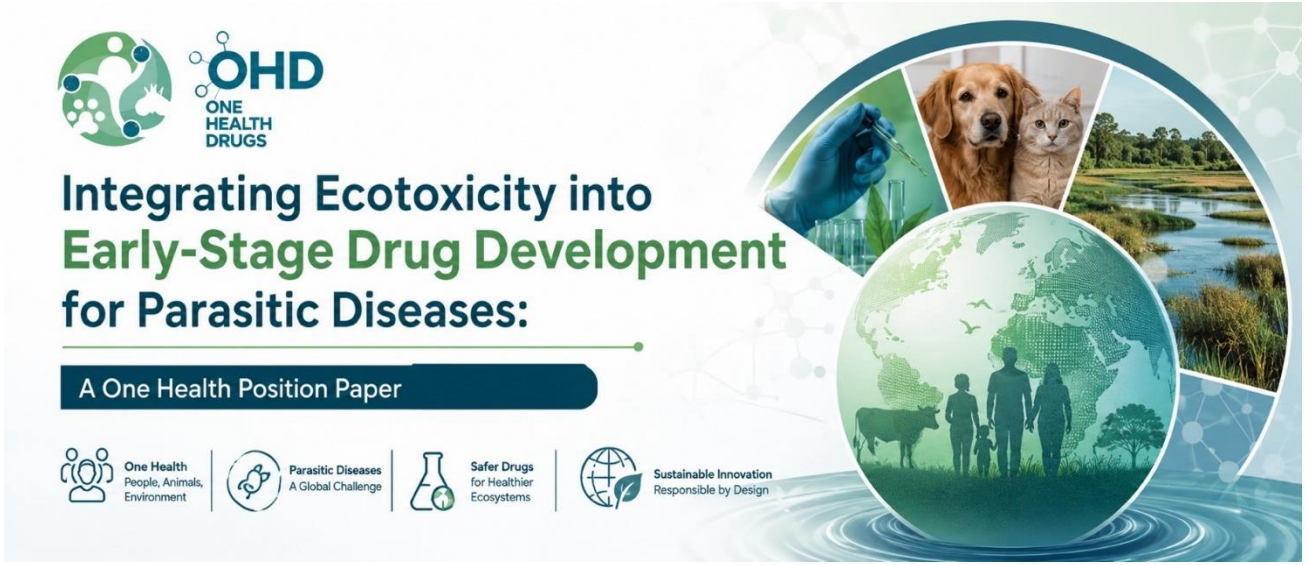
- This meeting is intended not as a formal conference, but as a journey through the assets we could establish.
- It will cover all completed work, including scientific activities and capacity-building actions involving a diverse range of stakeholders—such as scientists, young and senior researchers, SMEs, companies, communicators, and regulators—all of whom bring unique perspectives and mindsets to the table

Integrating Ecotoxicity into Early-Stage Drug Development for Parasitic Diseases: A One Health Position Paper

Action / network: COST Action CA21111 (OneHealthDrugs — OHD)

Date: July 2026





1.3.6 What This Paper Is — and Is Not

It IS: a structured, evidence-informed, multi-stakeholder position on integrating ecotoxicity into early-stage Parasitic Diseases discovery, with actionable, proportionate recommendations bounded by the available evidence.

- It IS NOT a systematic review: the evidence is assessed for relevance, quality and policy applicability, but the paper does not apply PRISMA-type methodology or quantitative synthesis.
- It IS NOT regulatory guidance: it does not carry the legal authority of EMA guidelines or EU instruments. It is a community position advocating regulatory evolution — and that distinction is intentional.
- It IS NOT a claim of universal agreement: disagreements are handled transparently; the positions represent the majority view of the co-creation group, not the elimination of dissent.

1.9 Identification of Target Audiences

On board

Research teams and medicinal chemists — technical guidance on 'benign by design', green chemistry metrics and in silico prediction of persistence and bioaccumulation.

Industry R&D leadership and executives — how environmental sustainability drives long-term value, reduces operational risk and achieves cost savings.

Not yet

This paper is prepared by a stakeholder team of academic researchers, experts familiar with ERA procedures in national regulatory bodies, pharmaceutical and representative organisations.

Its primary target audiences are regulatory entities such as the European Medicines Agency (EMA) and the European Commission. It is further tailored to:

- Regulatory affairs and compliance professionals — how early-stage data facilitates regulatory readiness under the 2024 EMA update.
- Funders and ESG investors — criteria to evaluate a pipeline's sustainability credentials under frameworks such as the Sustainable Finance Disclosure Regulation (SFDR).
- Policymakers and healthcare educators — a basis for curricula and policy incentives supporting Green Pharmacy.

The structure

THE FOUR PILLARS — THE EVIDENCE BASE

2.1

Pillar 1 — Empirical Field Evidence (Practice Reality)

- Real-world implementation data
- Testing in actual conditions
- Performance metrics from pilot projects

2.2

Pillar 2 — Environmental scientific evidence (ecological legitimacy)

- Scientific validation of benefits
- Long-term ecological impact studies
- Ecosystem health assessments

2.3

Pillar 3 — Regulatory Gap Analysis (Structural Issues)

- Assessment of existing laws
- Identifying policy barriers & opportunities
- Recommendations for legal frameworks

2.4

Pillar 4 — Innovation and Feasibility (The "Doable" Now)

- Practical & scalable solutions
- Technical & economic viability
- Readiness for implementation

DEFINITION — The Early Integration Framework

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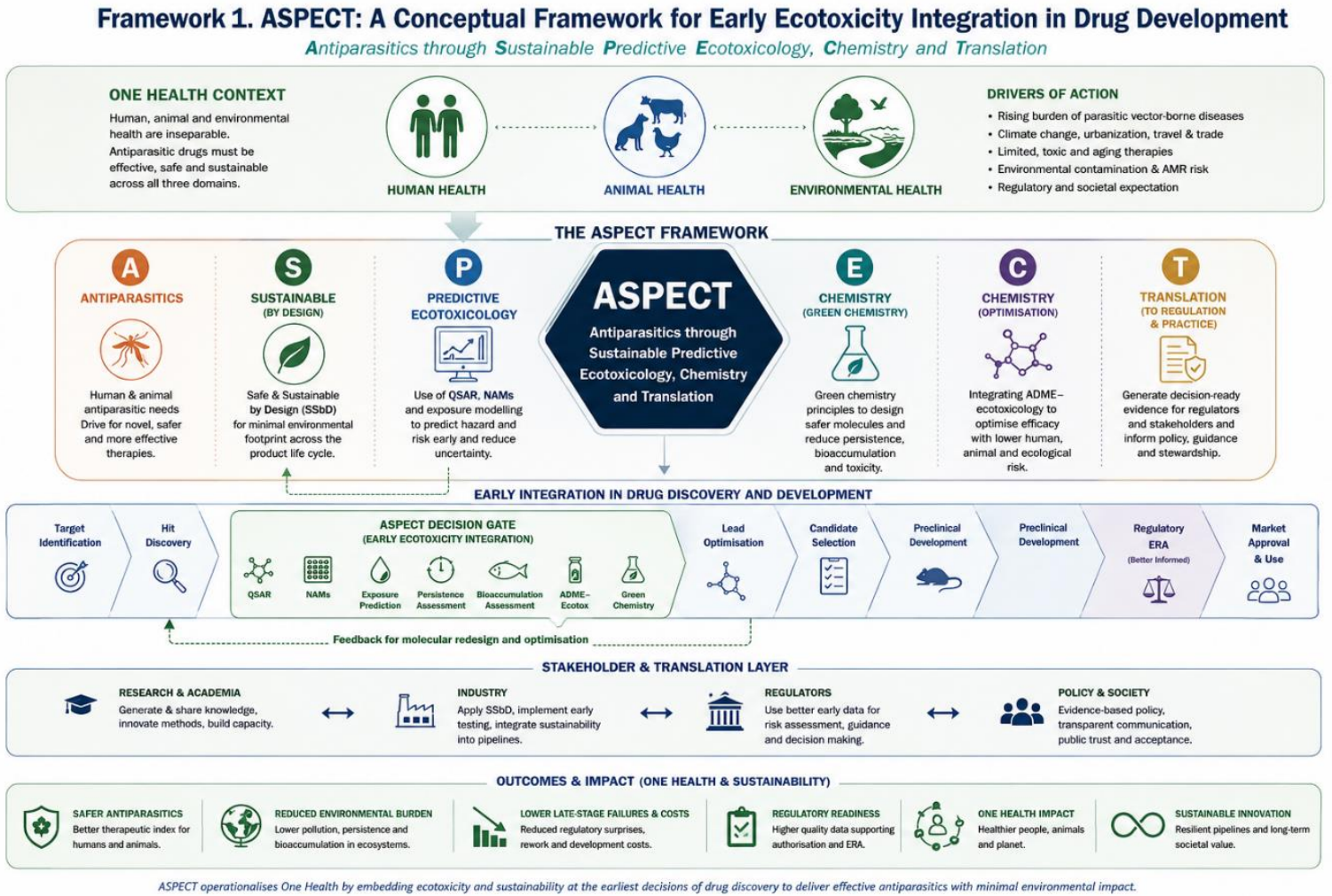
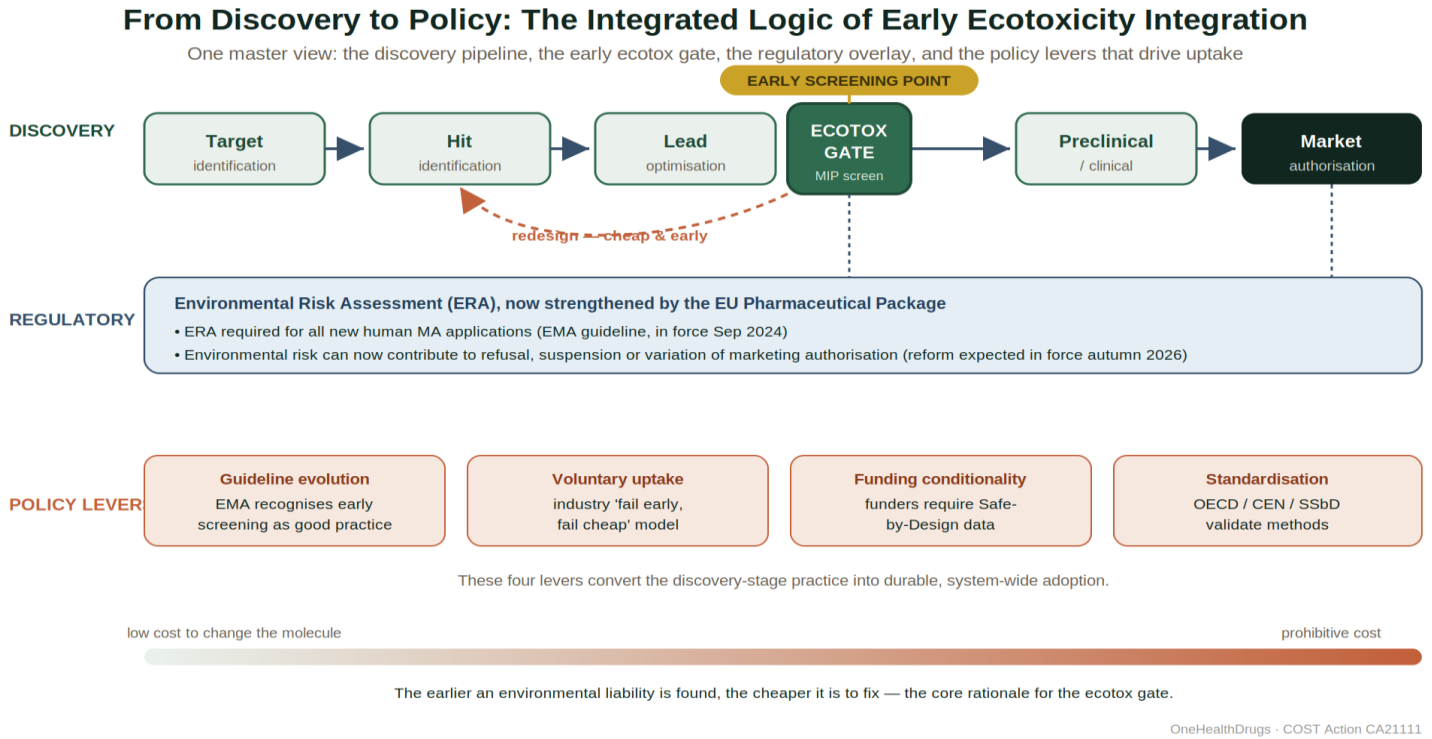
The Early Integration Framework is the systematic consideration of environmental fate and ecotoxicity at the earliest decision points of drug discovery (target identification, hit-to-lead and lead optimisation), so that a molecule's likely environmental behaviour informs its design before major preclinical and clinical investment is committed.

It operates through a defined screening point (the ecotoxicity gate) and a minimal agreed dataset (the Minimum Information Package, MIP). Candidates flagged as higher-risk are redesigned or deprioritised early; those that pass proceed with staged escalation.

It is a decision-support layer for discovery scientists. It does not replace the statutory ERA required at marketing authorisation, does not impose a market ban, and creates no new disclosure obligation unless a candidate proceeds to authorisation.

1.10 Conceptual Framework for Early Ecotoxicity Integration in Drug Development





Master figure *— The integrated logic of early ecotoxicity integration: the discovery pipeline, the early ecotox gate, the strengthened regulatory overlay (ERA), and the four policy levers that convert discovery-stage practice into system-wide adoption.*

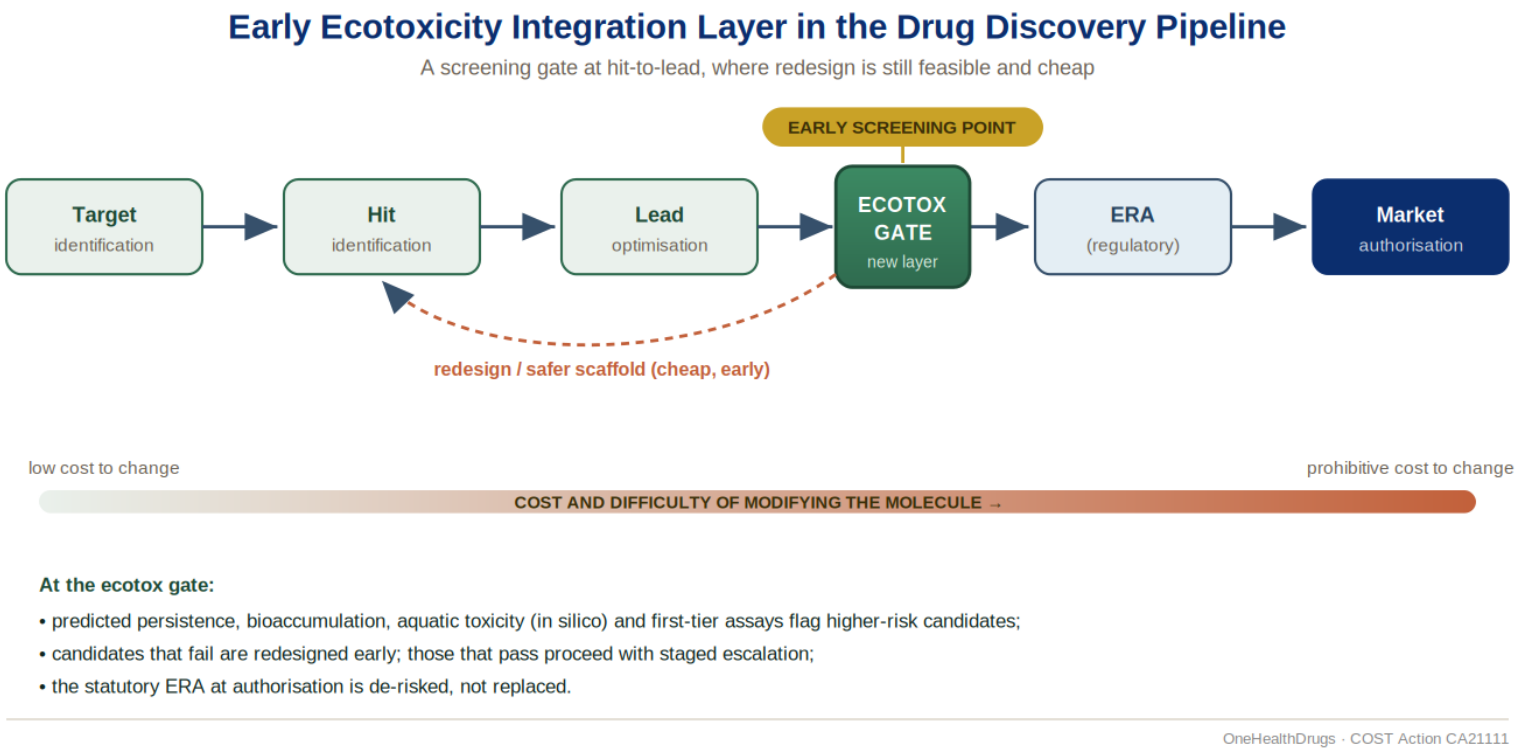


Figure 9 The Early Ecotoxicity Integration Layer in the drug discovery pipeline: a screening gate at hit-to-lead flags higher-risk candidates for redesign while modification is still feasible and cheap; it de-risks, but does not replace, the statutory ERA.

3.4 Implementation Roadmap and 2026–2027 Pilot

HOW THIS ACTUALLY GETS IMPLEMENTED — the mechanism chain

Adoption does not depend on a single legislative act. It advances along a chain of reinforcing mechanisms:

1. Evidence and feasibility (this paper + the 2026–2027 pilot) demonstrate that early screening works and is affordable.
2. Guideline recognition: EMA acknowledges early screening as good practice within ERA-related guidance, lowering the risk of voluntary adoption.
3. Voluntary industry uptake: companies extend the 'fail early, fail cheap' model already used in Animal Health to human PDis discovery, because it reduces their own late-stage risk.
4. Funding conditionality: funders and ESG investors require Safe-by-Design data as a grant or investment condition, reaching academic and SME actors directly.
5. Standardisation: OECD, CEN and the SSbD framework validate and standardise the methods, turning practice into a durable, comparable norm.

Each link makes the next easier. The role of the OHD network is to trigger the chain by supplying the evidence at step 1.

- This paper is evidence-informed and feasibility-driven; it does not claim full regulatory endorsement of early-stage tools, and separates what is validated from what remains predictive. It avoids overreach by keeping long-term coalition governance out of scope and focusing on deliverable construction and near-term adoption. Data confidentiality is handled by using category-level tool descriptions unless explicit permission is given to name proprietary elements.

4. Who Should Act — Stakeholder Map and Calls to Action

Stakeholder	Why this paper matters to them	Specific ask
European Medicines Agency (EMA)	The new Pharma Package strengthens ERA and makes environmental risk a possible refusal ground; the 2024 ERA guideline is already in force.	Recognise early-stage screening as best practice that de-risks the ERA EMA will require; reference it in implementation guidance.
European Commission (DG SANTE, DG ENV)	The UWWTD already imposes €1.2bn/yr in polluter-pays costs; >90% of micro-pollutants are pharma/cosmetic.	Support early environmental design as the lowest-cost way to reduce micro-pollutant load at source; connect Pharma Package and SSbD implementation.
Industry R&D leadership	Bringing a drug to market costs ~$2.3bn; ~90% of clinical candidates fail; environmental risk can now gate authorisation.	Adopt early environmental screening as internal decision-support; 'fail early, fail cheap' as in Animal Health.
ESG investors / funders	ESG assets are projected at ~$33.9tn by 2026; ESMA's 80% fund-naming rule pushes capital toward demonstrably sustainable assets.	Treat environmentally-screened pipelines as an investability criterion; require Safe-by-Design data in grant conditions (R4, R6).
Academic / SME discovery teams	Most groups are small with limited ecotox capacity; SSbD now offers tiered, SME-friendly implementation.	Apply low-cost in silico screening and the shared MIP template; participate in the 2026–2027 pilot.
Veterinary & research educators	62% of vets never received environmental training; the prescribing gap is an education gap.	Embed environmental stewardship in curricula and CPD.

Here, open consideration about the financial sustainability and lack of information make it difficult to find solid conclusion

- **5. The Economic and ESG Case**
- **5.1 The cost-of-failure case ('fail early, fail cheap')**