Pharmaceuticals Strategy for Europe: A Call for Continuous Improvement towards Environmental Protection

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The European Commission recently adopted a proposal for **new pharmaceutical legislation**

2006
EMA published guideline for environmental risk assessment

2018
EMA published *draft* updated guideline for ERA. It will come into force in September 2024

2020
The EU launched its Pharmaceutical Strategy for Europe, promising *greener medicines*

April 2023
EC accepted proposal for new Regulation and Directive to replace general pharma legislation

November 2023
Public consultation on new Regulation and Directive closed

It offers **enhanced protection against environmental risk…**

Current legislation	Focuses largely on use and disposal phases	ERA cannot be used as basis for refusal of market authorisation	Products that entered environment pre-2006 don't need ERA	ERA only required at market authorisation stage	Labelling requirements limited – PBT, vPvB	Antimicrobial resistance (AMR) is not in scope
Proposed legislation	Requirement to assess environmental impact of **entire product lifecycle**	Authorities can **refuse or vary an authorisation based on environmental risk** that can't be mitigated	**ERA must be carried out on pre-2006 products**, within 30 months of regulation coming into force	ERA must be **updated with new information** without undue delay	Substances that are identified as **PMT, PBT, vPvM, vPvB or endocrine disrupting** must be identified	**Risk of AMR must be assessed** and "stewardship plan" included to monitor development of AMR

…but there is room for **continuous improvement**

More holistic effects testing
Wider range of endpoints, e.g. behavioural; use of *in silico* modelling to reduce the need for *in vivo* studies; MoA catalogues and AOPs

Mixtures risk assessment
Need for pharma-specific Mixture Assessment Factors (MAFs)

Accounting for environmental heterogeneity
Bioavailability dependence on pH, DOC, temperature; local hotspots; climate change

+ **Open data requirements**
ERA monograph and register of ERA studies

AMR: Antimicrobial Resistance | **EC:** European Commission | **EMA:** European Medicines Agency | **ERA**: Environmental Risk Assessment | **PBT/PMT:** Persistent, Bioaccumulative/Mobile, Toxic | **vPvB/vPvM:** Very Persistent, very Bioaccumulative/Mobile

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Establishing safe and sustainable pharmaceutical life cycles by design

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