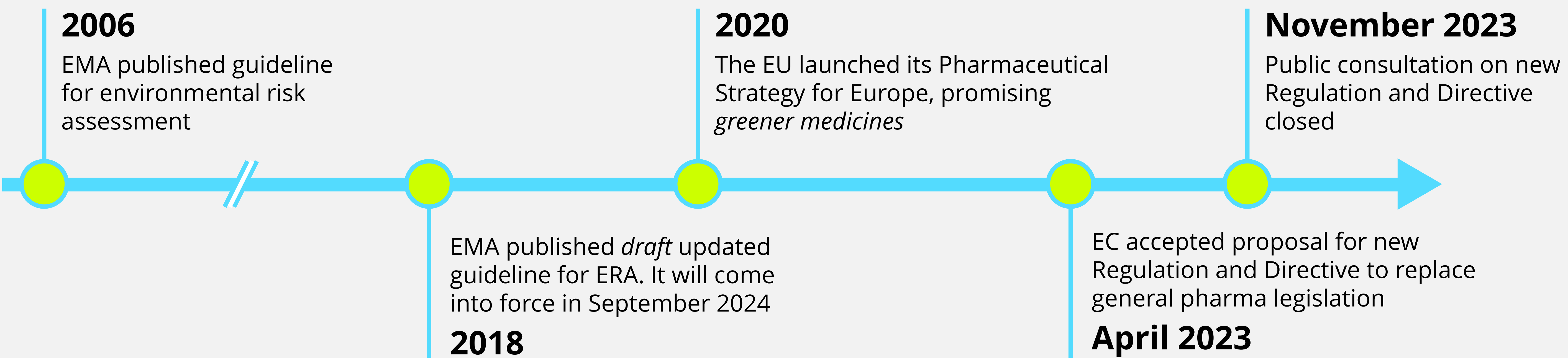


Sam Harrison¹, Catherine Barnett¹, Maria D. Pavlaki², Stephen Lofts¹, Sarah Roberts¹, Stephen Short¹, Madalena Vieira², Susana Loureiro², Dave Spurgeon¹

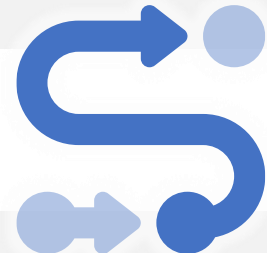
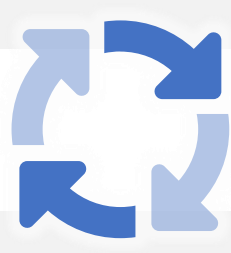
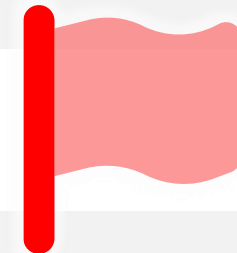
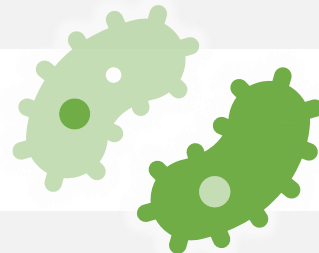
¹ UK Centre for Ecology & Hydrology
² Centre of Environmental and Marine Studies, Department of Biology, University of Aveiro



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



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

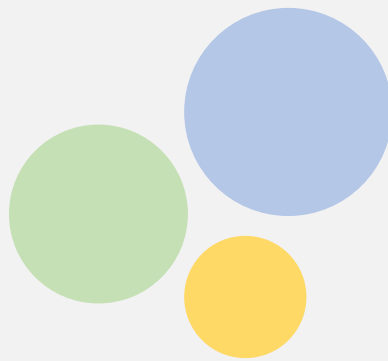
Current legislation	Focuses largely on use and disposal phases	ERA cannot be used as basis for refusal of market authorisation	Products that entered environment pre-2006 don't need ERA	ERA only required at market authorisation stage	Labelling requirements limited – PBT, vPvB	Antimicrobial resistance (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**

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



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

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