

Pharmaceutical innovation, regulation and regulatory innovation: a pathway perspective

Jarno Hoekman
j.hoekman@uu.nl

Innovation Studies, Copernicus Institute of
Sustainable Development Utrecht University

Pharmaceutical legislation: Highway to innovation?

- High-quality, safe and effective infrastructure...?
- Need for speed...?
- Capacity to shape pathways that direct pharmaceutical innovation



Pathway metaphor

- Interconnecting pan-European highways, 'route nationals' and back alleys
- Traffic rules and control systems *and* road user practices
- Transitioning to sustainable technologies and modal shifts

How do we envisage pharmaceutical futures?

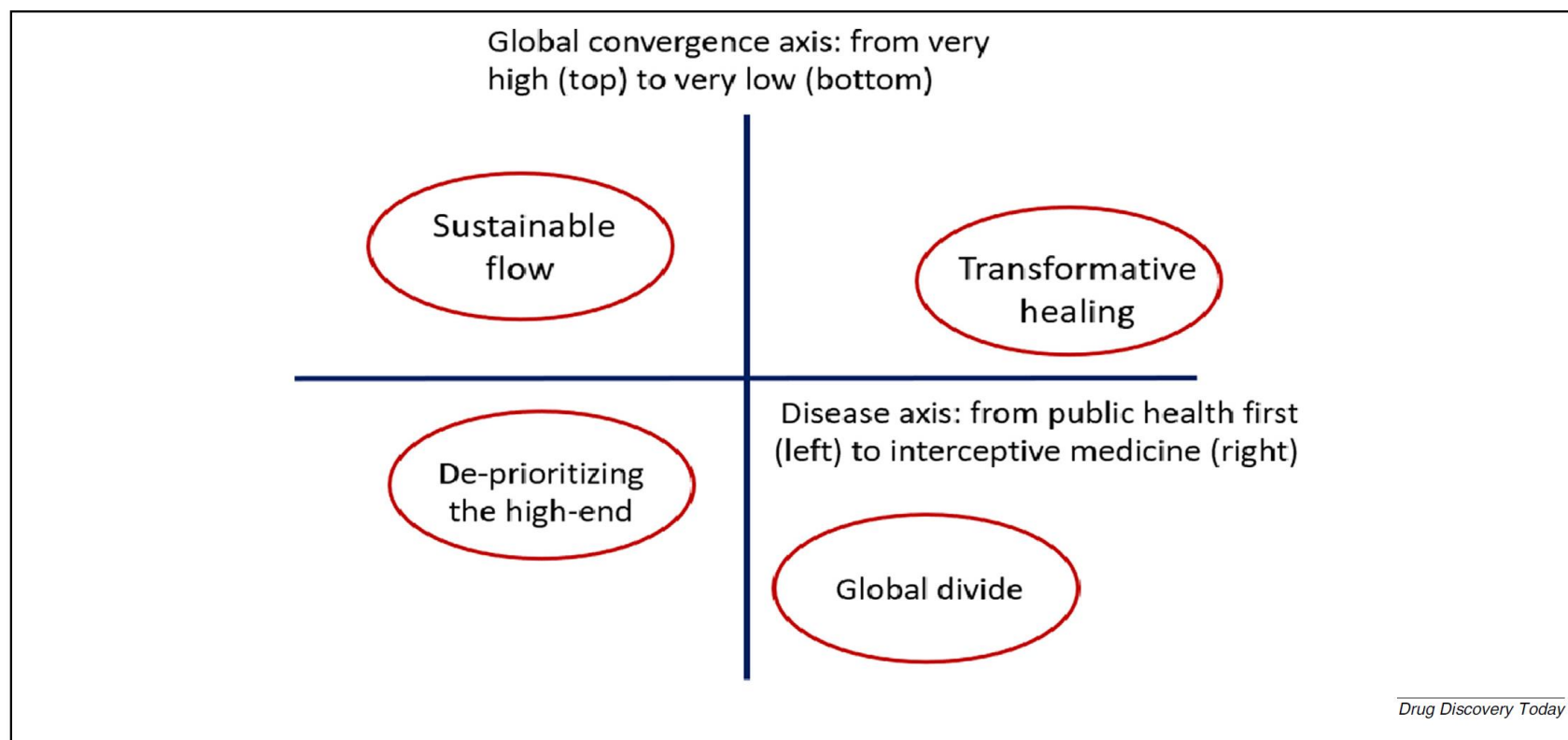


FIGURE 1

Four scenarios for the future of medicines and social policy in 2030.

Leufkens HG, Kusynova Z, Aitken M, Hoekman J, Stolk P, Klein K, Mantel-Teeuwisse AK, 2022. *Drug Discovery Today*, 27 (8).

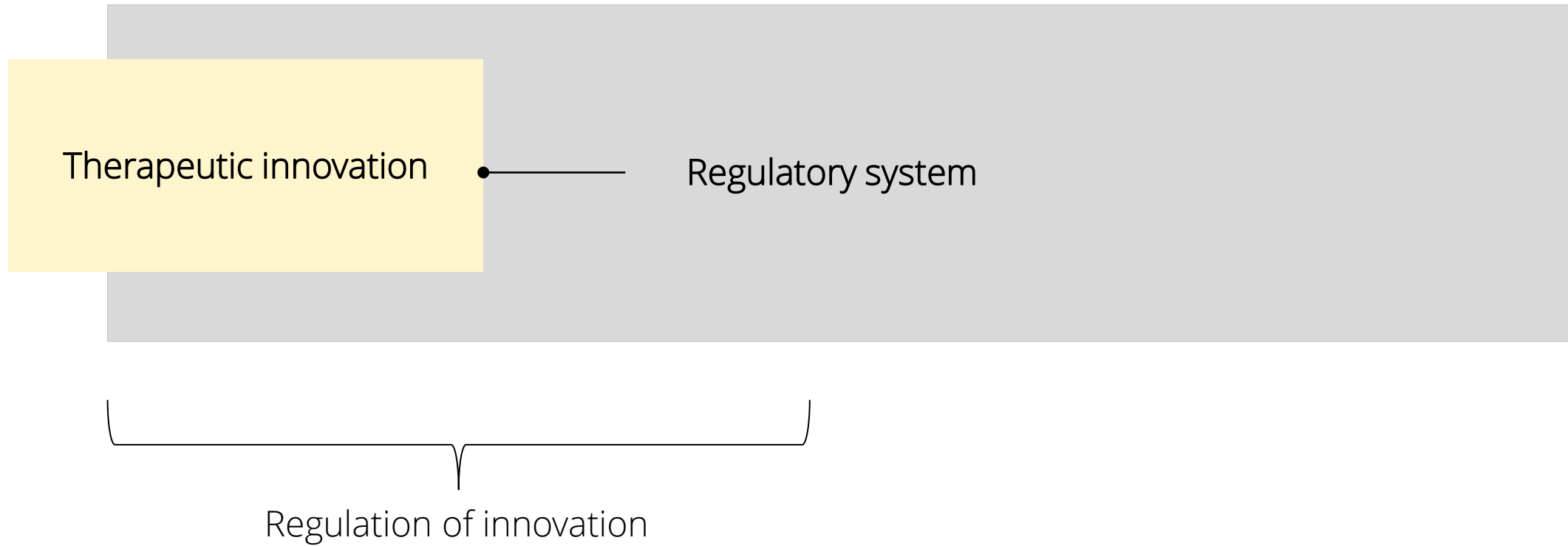
How to think about innovation in and of the regulatory system?



Legislative change in the regulatory system...

- ...is not only about formal rules but also informal rules and social and organizational practices of implementation
- ... needs to be embedded in a regulatory system that performs functions over the medicinal product life-cycle
- ...requires capacities and mindsets for change as integral function of the system

Regulation of innovation



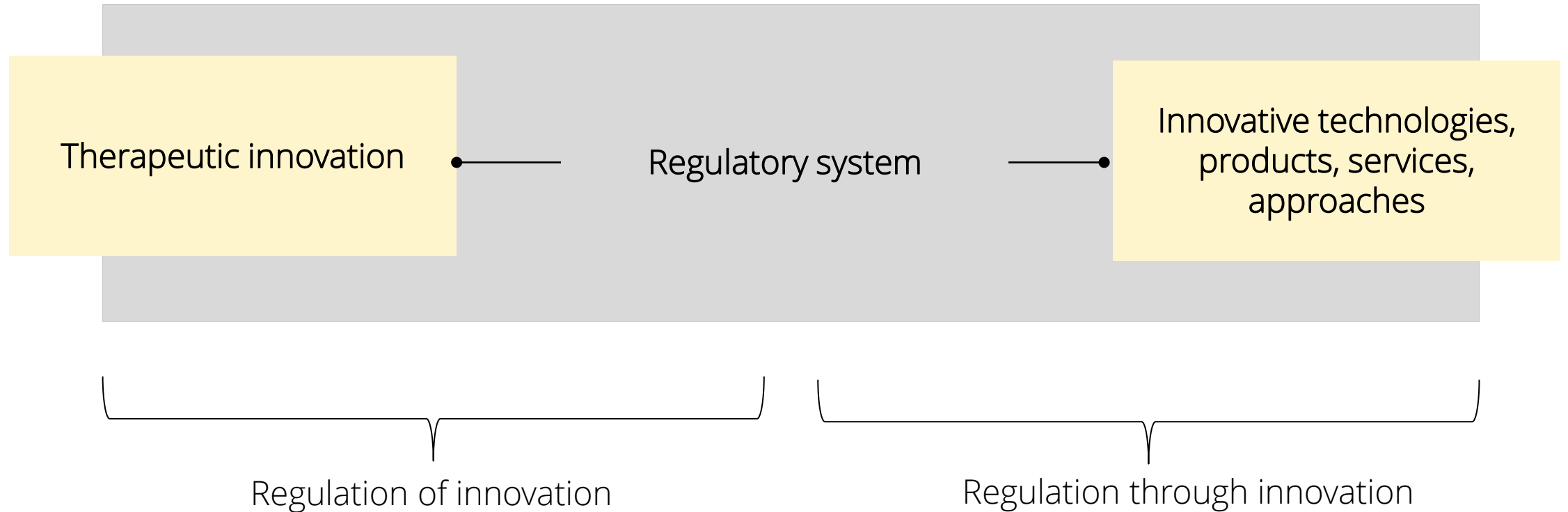
Regulation of innovation

- Promote innovation
(e.g., *IPR, data exclusivity*)
- Shape innovation
(e.g., *safety, quality, efficacy*)

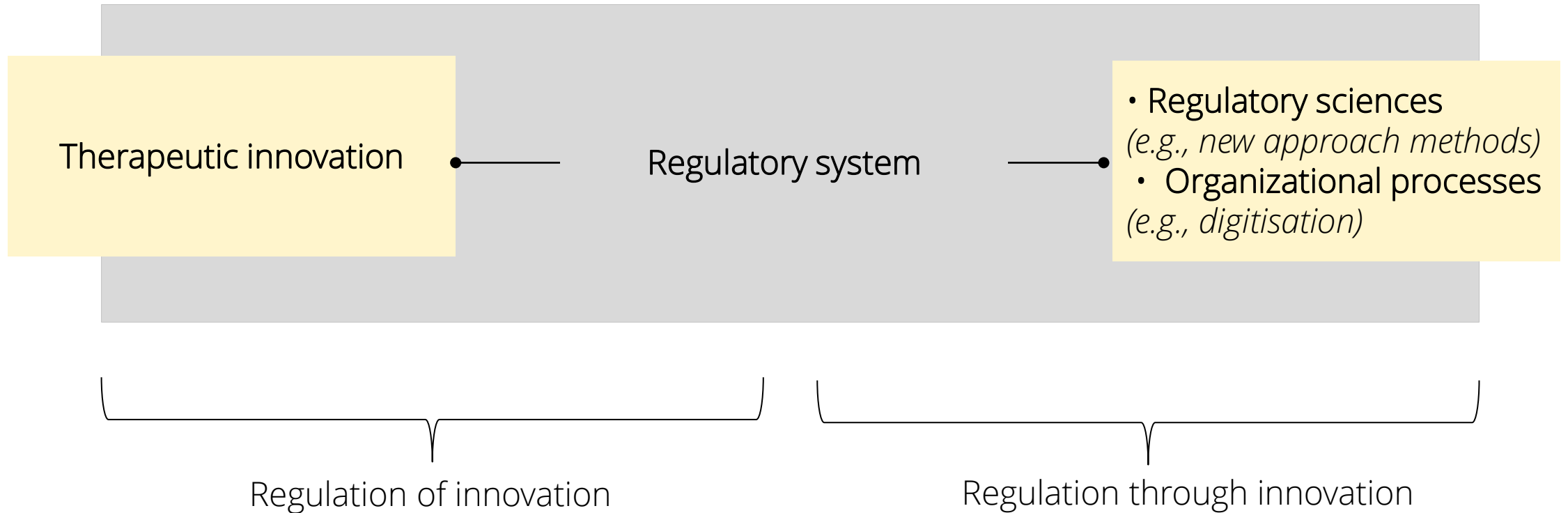
Regulatory system

Regulation of innovation

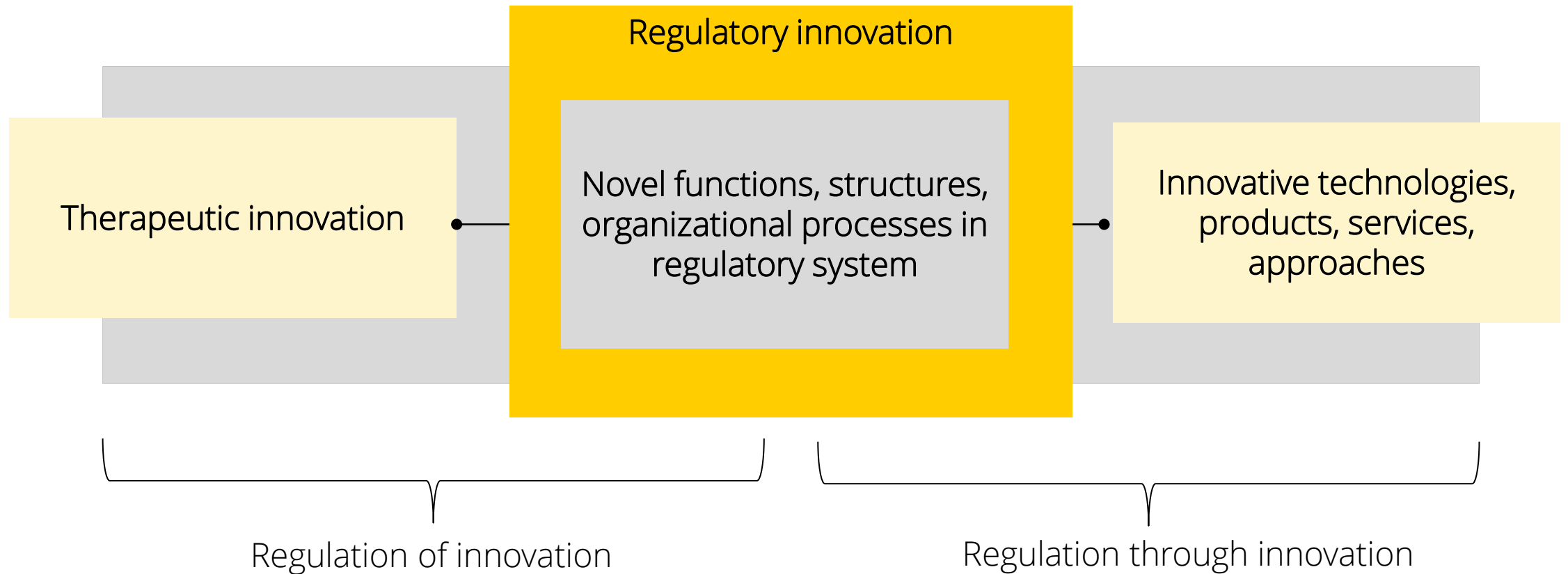
Regulation through innovation



Regulation through innovation



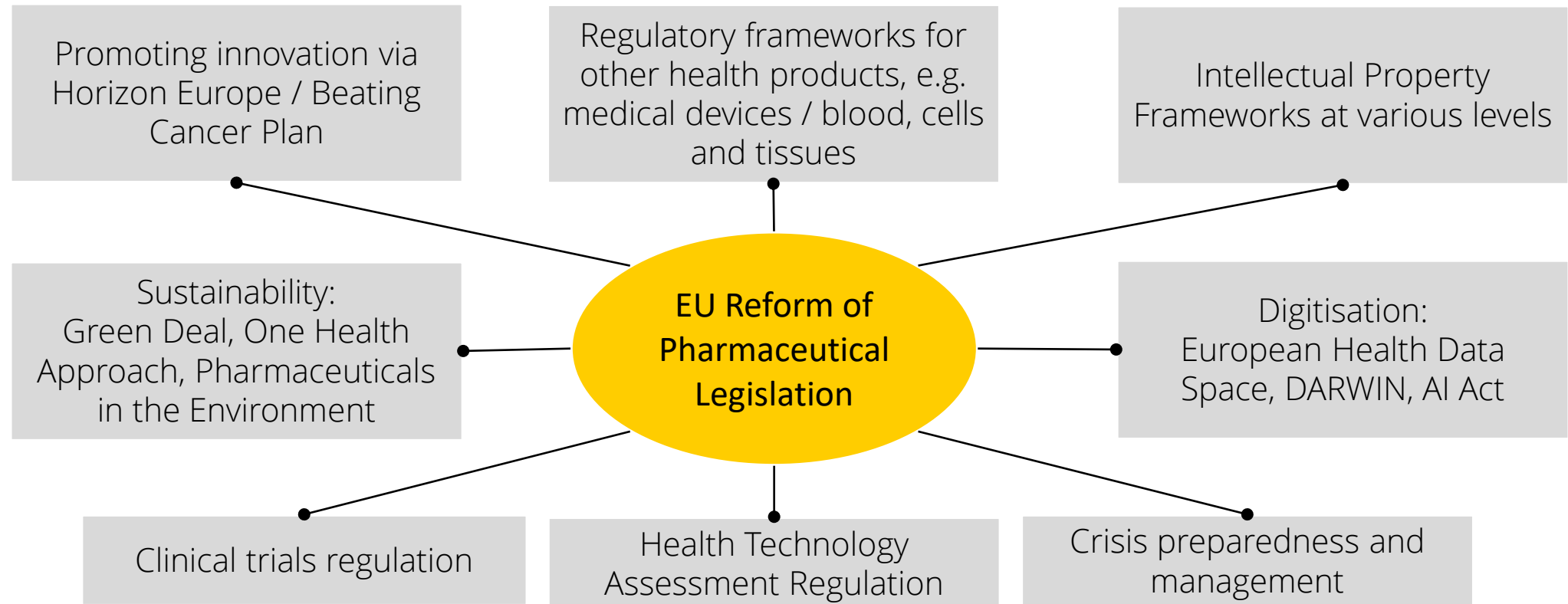
Regulatory innovation



Innovation in the context of pharmaceutical regulation

	Regulation of innovation	Regulation through innovation	Regulatory innovation
Main innovators	Firms	Academia and firms	Regulators
Main goals	Correct market failure	Qualification (fit-for-purpose, patient-centered)	Dealing with uncertainty and complexities
Main instruments	Incentives and compliance	Standard-setting	Experimentation and learning
Examples	• Data exclusivity • Unmet medical need • Environmental RA • Shortage measures • AMR vouchers	• New approach methods • Real-world data • Data-sharing (transparency) • Digitisation (ePI)	• Sandbox approaches • Integrated pathways • Scientific opinion on data from non-profit entities • 'Future-proofing'

Interactions with policy and innovation system



Providing directionality for emergent innovations

- Societal goals are leading, innovation is not a goal in itself
- Attention to gaps and interfaces in frameworks
- Acknowledgement of complexity, uncertainty and ambiguity
- Broad and early stakeholder involvement incl. patients and publics
- Adaptive capacity: e.g., balancing use of hard and soft laws
- Anticipatory capacity: e.g., visions and foresight

How to think about the anticipated effects of the reform of EU pharmaceutical legislation on innovation?

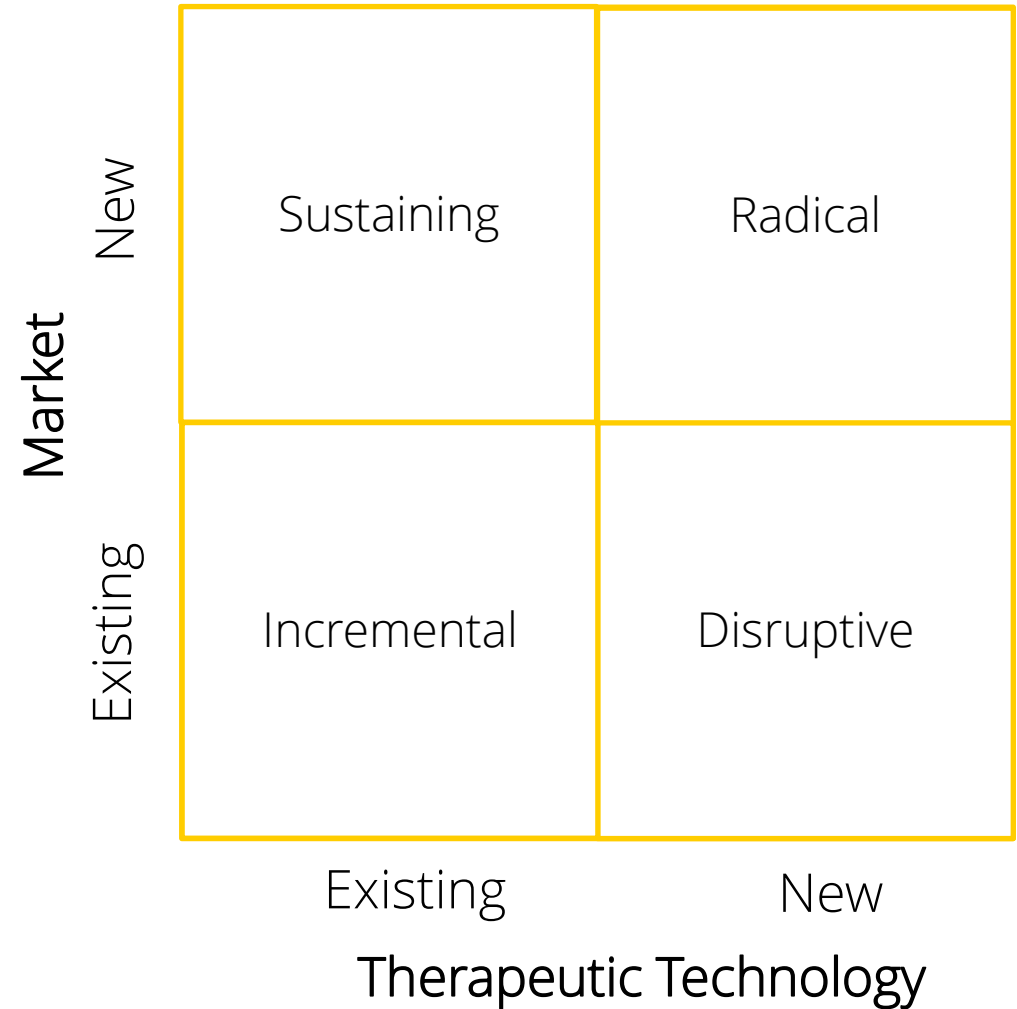
Broad systemic notion shows that effects on innovation can be anticipated in relation to all reform objectives

EU Pharmaceutical Legislation Reform: specific objectives

- *Make sure all patients across the EU have timely and equitable access to safe, effective and affordable medicines*
- *Enhance the security of supply and ensure medicines available to patients irrespective of where they live in the EU*
- *Continue to offer an attractive and innovation-friendly environment for research, development and production of medicines in Europe*
- *Make medicines more environmentally sustainable*
- *Address antimicrobial resistance and the presence of pharmaceuticals in the environment through a one health approach (specific communication)*

Effects are likely to be varied and complex depending on:

- innovation type*
- innovator type*
- implementation dynamic*



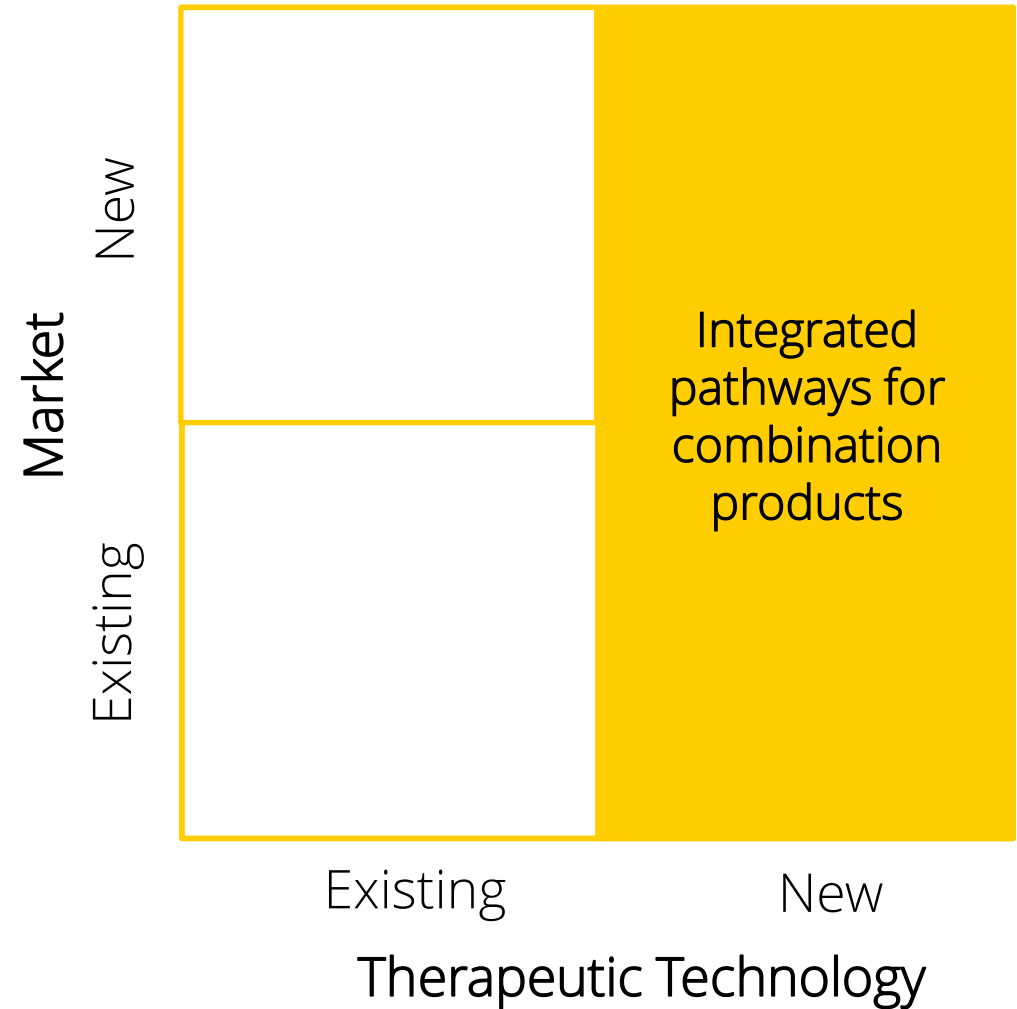
Effects are likely to be varied and complex depending on:

- innovation type*
- innovator type*
- implementation dynamic*

Market	New	Enable innovation by not-for-profit entities	
	Existing		
		Existing	New
		Therapeutic Technology	

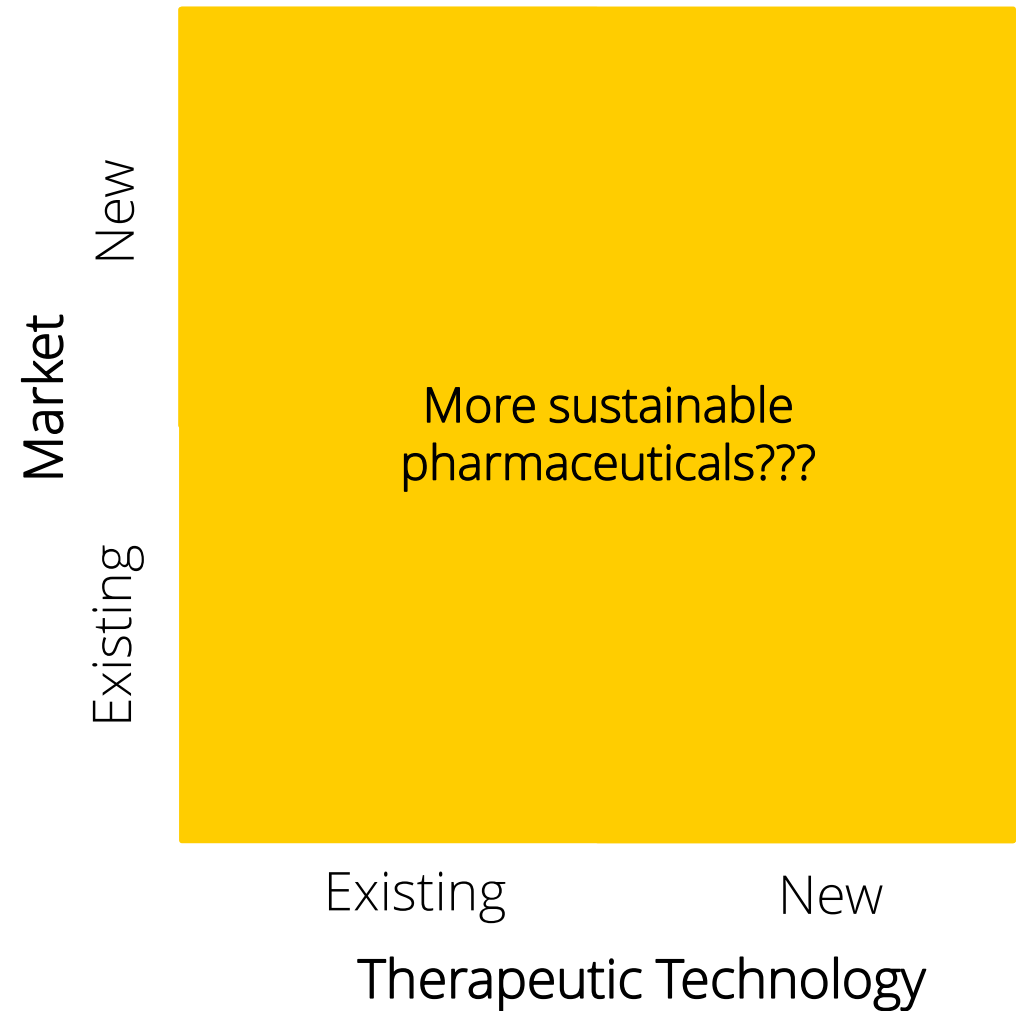
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Interdependencies are key in shaping pathways to direct innovation

Directing innovation	Regulation of innovation	↔	Regulation through innovation	↔	Regulatory innovation
Sustainable therapeutics	Enforcing environmental risk assessment		Environmental risk assessment through new approach methods		Environmental sustainability as part of benefit-risk balance
Patient-centered therapeutics	Definitions of unmet medical need and related incentives for organisations		Patient-reported outcomes and patient convenient trials		New ways for patient influence on decision-making

Thanks for your attention

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