
New Pharmaceutical Legislation:

Regulatory Sandboxes

Commission/EMA Workshop on
regulatory sandboxes

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European
Commission

#HealthUnion



Regulatory Sandboxes in pharma



The regulatory framework may not be fit for disruptive innovation, difficult to align speed of innovation with “speed” of legislative review cycles, while ensuring patients have breakthrough treatments



Future-Proofing Regulation

Prepares for the “unknown”, i.e for diseases, therapies and technologies that we cannot really imagine at the moment, but become a reality due to rapid technological and scientific progress which challenges the *status quo*



Mutual Learning

Creates valuable mutual learnings for regulators/developers



Regulatory Calibration

Informs adapted frameworks, future regulatory changes and avoids over- or under-regulation

Strictly controlled environment



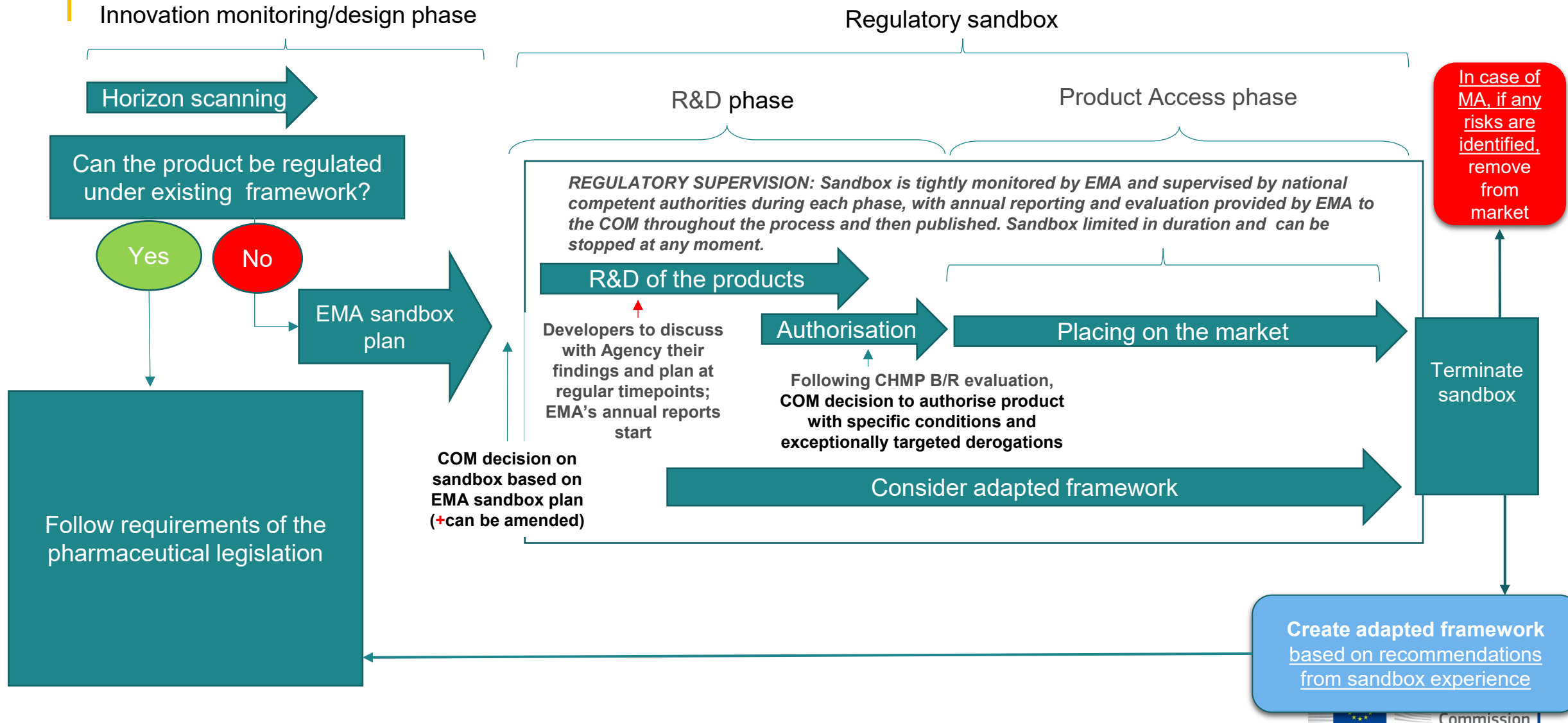
Regulatory sandbox – what it is

Aspect	What the legislation says
A Structured Experimental Space	A controlled framework enabling real-world testing of innovative technologies under direct supervision of the EMA and national competent authorities, with appropriate safeguards. (Recital 133; Art. 113(2))
A Response to Genuine Scientific Impasse	Triggered only where development and authorisation of an innovative product are genuinely impossible under ordinary requirements, due to the product's inherent scientific or technical characteristics or the methods related to it — not merely inconvenient or commercially suboptimal. (Recital 133a; Art. 113(1)(a))
A Tool for Proactive Regulatory Learning	Designed to enable regulators to gain real-world evidence and find the best regulatory responses to truly exceptional innovations at an early stage of development, particularly under conditions of high uncertainty. (Recital 133)
A Pathway for Targeted, Proportionate Adaptations	Allows specific, technically indispensable adaptations to certain requirements. Each adaptation must be limited to what is strictly necessary, duly justified, and not exceeding what the Commission Decision specifies. (Art. 113(2); Art. 114(3))
A Formally Governed Instrument	Established by a Commission Implementing Decision following an EMA recommendation and sandbox plan. The plan must include clinical, scientific and regulatory justification, risk mitigation measures, and a proposed timeline. (Art. 113(4)–(6))
A Springboard for Future Legislation	Learnings from a sandbox are capable of informing future changes to the legal framework. Annual EMA reports feed into potential legislative proposals or delegated acts. (Recital 135; Art. 115(4)–(5))
A Time-Limited and Revocable Framework	Every sandbox has a defined duration and expiry. It may be suspended or revoked at any time if conditions are no longer met or to protect public health or the environment. (Art. 113(7)(b); Art. 113(8))
Open to SMEs and Startups	SMEs and startups have the possibility to participate on a case-by-case basis, ensuring access is not limited to large pharmaceutical companies. (Recital 133)

Regulatory sandbox – what it is not

Aspect	What the legislation says
Not a Derogation from Quality, Safety & Efficacy	The core principles of quality, safety, and efficacy are non-negotiable and explicitly preserved throughout. The sandbox adapts how these principles are demonstrated — it cannot waive what they require. (Recitals 133a, 134, 135; Art. 113(2))
Not a Removal of Supervisory Powers	Regulatory sandboxes do not affect the supervisory and corrective powers of competent authorities. Where risks to public health are identified, authorities must take immediate measures to suspend or restrict product use. (Art. 115(1))
Not Available to Products Advanced in Development	The EMA shall not recommend a sandbox for a medicinal product already advanced in its development programme. The sandbox intervenes upstream — not as a remedial tool for late-stage products. (Art. 113(4))

Life of a sandbox



WISE NIGHT

Door technische problemen
is de activiteit geannuleerd;
Onze excuses.

À cause des problèmes
techniques, on a dû
annuler l'activité Sandbox.
Désolé.

Due to technical difficulties,
the sandbox has been
cancelled.
Our apologies.

Sandbox – Take away messages

- a regulatory sandbox is a means (to bring - or to test how to bring) innovative solutions in the area of medicines to the market, but not an end
- a regulatory sandbox is not just another pathway to authorisation
- a regulatory sandbox is not a tool to deregulate, but to *better* regulate innovation
- a regulatory sandbox is only successful with the full engagement of all actors involved
- a regulatory sandbox needs to start early in the development phase and should be open to all products concerned

Thank you



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