



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Regulatory sandbox in the new pharmaceutical legislation

21 September 2026, 13:30 – 17:00 (CEST)

EMA, Amsterdam / live broadcast

A regulatory sandbox establishes a time-limited framework in which developers can design, validate, and test innovative medicines or methodologies in a controlled, real-world environment, under strict regulatory oversight.

The reform of the EU pharmaceutical legislation includes regulatory sandboxes as a tool to test, under the direct supervision of the competent authorities, adapted requirements for innovative medicines that cannot be developed under current rules.

This workshop, jointly organised by the European Commission (EC) and the European Medicines Agency (EMA) will bring together medicines developers, regulators, and policy-makers to discuss aspects of the implementation of regulatory sandboxes, how sandboxes work, and what is necessary to implement and execute them effectively. In particular, the objectives of this workshop are to:

- Present the regulatory sandbox concept as laid out in the revised pharmaceutical legislation
- Discuss key elements for the implementation of regulatory sandboxes for medicines, specifically:
 - Horizon scanning
 - Regulatory sandbox plan
 - Transparency and communication

Regulatory sandbox in the new pharmaceutical legislation

Co-chaired by Florian Schmidt (EC) and Falk Ehmann (EMA)

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13:30	Welcome and opening speech	
	Emmanuel Cormier (EMA)	10 min
13:40	Session 1: Introducing the concept of regulatory sandbox	
	Regulatory sandboxes in the new pharmaceutical legislation <i>Florian Schmidt, EC</i>	15 min
	Implementation of regulatory sandboxes for medicinal products <i>Valentina Cordò, EMA</i>	15 min
	Regulatory sandboxes: a perspective from the IHI BRIDGE consortium <i>IHI BRIDGE representatives</i>	15 min
	Q&A	15 min
14:45	Session 2: Break-out sessions	
	Break-out session I Horizon Scanning: looking for candidates for a regulatory sandbox Chaired by Valentina Cordò (EMA)	
	Break-out session II Regulatory sandbox plan Chaired by Kristina Larsson (EMA)	
	Break-out session III Transparency and communication in a regulatory sandbox Chaired by Florian Schmidt (EC)	

15:45 **Coffee break**

16:00 **Session 3: Feed-back from break-out sessions (BOS) and discussion**

Co-chairs: Falk Ehmann (EMA) and Florian Schmidt (EC)

BOS I – outcome of discussion followed by Q&A

BOS II – outcome of discussion followed by Q&A

BOS III – outcome of discussion followed by Q&A

17:00 **Closing remarks**

Olga Solomon (EC) / Michael Berntgen (EMA)