EMA
EUROPEAN MEDICINES AGENCY

Regulatory Sandbox

Initial considerations

Valentina Cordò

Regulatory Science and Innovation Task Force

Disclaimer

This presentation is meant to give a general overview of the agreement reached between the co-legislators. While the content is final, certain details, such as legal references cited in this document, may still change after the lawyer linguistic check of the legal texts and therefore may differ slightly from the official versions of the two acts which will be published in the EU Official Journal by end 2026.

Regulatory sandbox

'Regulatory sandbox' is a regulatory framework during which it is possible to develop, validate and test in a controlled environment innovative or adapted regulatory solutions that facilitate the development and authorisation of innovative products which are likely to fall in the scope of this Regulation, pursuant to a specific plan and for a limited time under regulatory supervision *(art 2.10 Regulation)*

Regulation - Chapter IX:

- Art 113: Regulatory sandbox
- Art 114: Products developed under a sandbox
- Art 115: General sandbox provisions

Provisions will become effective at the entry into force of the new legislation (likely Q4 2026)

Regulatory sandbox – current text

- **it is not possible to develop and authorise** the medicinal product or category of medicinal products in full compliance with the current legislation requirements due to scientific or regulatory challenges arising from characteristics or methods related to the medicinal product or due to the scientific or technical characteristics inherent to the medicinal product → **certain targeted and technical adaptations to the requirements are considered indispensable**

- the characteristics or methods are likely to, based on available scientific evidence, positively and distinctively **contribute to the quality, safety or efficacy of the medicinal product** or category of medicinal products **or provide a major advantage contribution to patient access to prevention, diagnosis, treatment, or patient care**

- **The sandbox plan** should set out **a clinical, scientific and regulatory justification** for the regulatory sandbox, including an overview of the **regulatory requirements that need to be adapted**.

In practice

- A regulatory sandbox is **exceptional**
- Technical adaptations to requirements/regulations are **indispensable**
- EMA will need to develop a **sandbox plan**
  - Needed adaptations and justifications
  - Timeframe
  - Evidence generation plan
- EMA in consultation with the network, will provide a **recommendation to the EC** that will establish a sandbox

A sandbox is NOT:

- ❖ Another early interaction tool/advice mechanism offered by EMA
- ❖ Just another marketing authorisation pathway
- ❖ A way to lower the regulatory standards

Identification of possible candidates:

EMA Innovation Task Force (ITF) offers a platform for innovators to discuss potential cases/proposals in an informal and non-binding way

Working towards regulatory sandboxes

The European Commission, in its legal proposal for the revision of the EU pharmaceutical framework , has included a proposal for a 'regulatory sandbox'.

A **regulatory sandbox** is a controlled framework that allows the testing of an innovative development in a controlled environment for a limited period of time.

The creation of a regulatory sandbox might be necessary when it is not possible to develop a medicinal product unless targeted adaptations or derogations to certain requirements are applied, under direct supervision of the relevant competent authorities.

The EC legal proposal is still under discussion with the European Parliament and Council of the European Union. A final decision on inclusion of the regulatory sandbox in the EU pharmaceutical framework has not yet been reached.

However, as part of EMA's monitoring horizon scanning on future innovative products, informal ITF meetings with medicine developers may help to identify, at an early stage during development, potential case studies that could inform a regulatory sandbox approach in the future (if endorsed by the co-legislators). These meetings are:

- Early informal dialogue between medicine developers and regulators to gather information
- Not a pre-assessment of product eligibility for a future regulatory sandbox approach or any other procedure.

EC/EMA multi-stakeholder workshop on Regulatory Sandboxes

- **21 September** (13:00-17:00 CEST) at EMA premises
- Attendance on invitation only. Live broadcast on the EMA website
- Target audience:
  - Innovators/developers (industry, SMEs, academia, consortia, manufacturers)
  - EU network (EC, NCAs)
- Topics to be discussed: sandbox concept under the new pharmaceutical legislation, horizon scanning, sandbox plan, transparency and communication
- Aim: early stakeholder engagement on the implementation of such a new concept

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Thank you

valentina.cordo@ema.europa.eu

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