Utilizing Regulatory Sandboxes to Promote Innovative Therapies for Patients

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What if a New Innovative Therapy…

- Isn’t best regulated by current regulations
- Current regulations didn’t contemplate new technology
- Innovative products need different approach

Need a solution that…

- Encourages innovation
- Streamlines regulatory and scientific device evaluation,
- Expedites the delivery of novel, important, safe and effective innovative medical devices to patients.

Sandbox Play

- Defined area or “box” to play
- Play freely without worry to make a mistake or mess
- Try out new ideas and let imagine run free
- Easily collaborate with others
- Exploration and creative thought

Regulatory Sandbox

- Safe and prescribed area that is used for new ideas
- Regulatory sandboxes are a structured form of regulatory flexibility
- Ability test innovative products or services
- Regulatory sandboxes are typically administered by regulatory authorities.
- The innovative nature of sandboxes may require approaches and competences that differ from those required for traditional regulatory approaches

Ulilizing Regulatory Sandboxes

1

Framework for negotiated rulemaking
Framework set up for experimenting with technologies in view of developing new and updating existing legislation, implementing or delegated acts, guidance, standards, and administrative provisions.

E.g., FDA's Pre-certification program, MHRA's Airlock, Singapore's LEAP for telemedicine

2

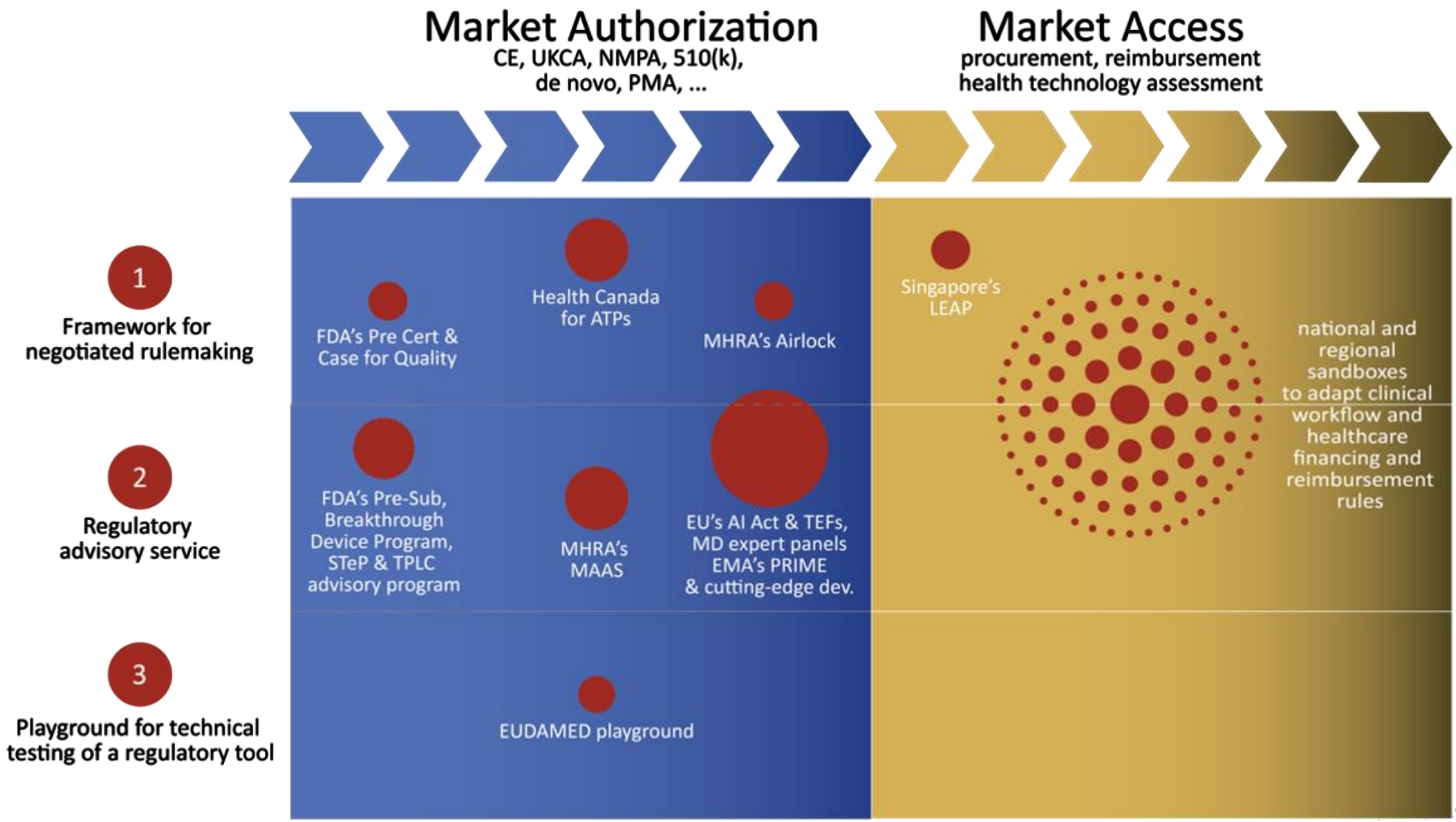
Regulatory advisory service
Advisory service providing scientific, regulatory, legal, and ethical advice on market authorization and/or market access of products and services. It may include a testbed to experiment with technology and gain insight into the extent of regulatory compliance.

E.g., MHRA's one-stop-shop for AI developers and users, EU's proposed AI Act regulatory sandboxes

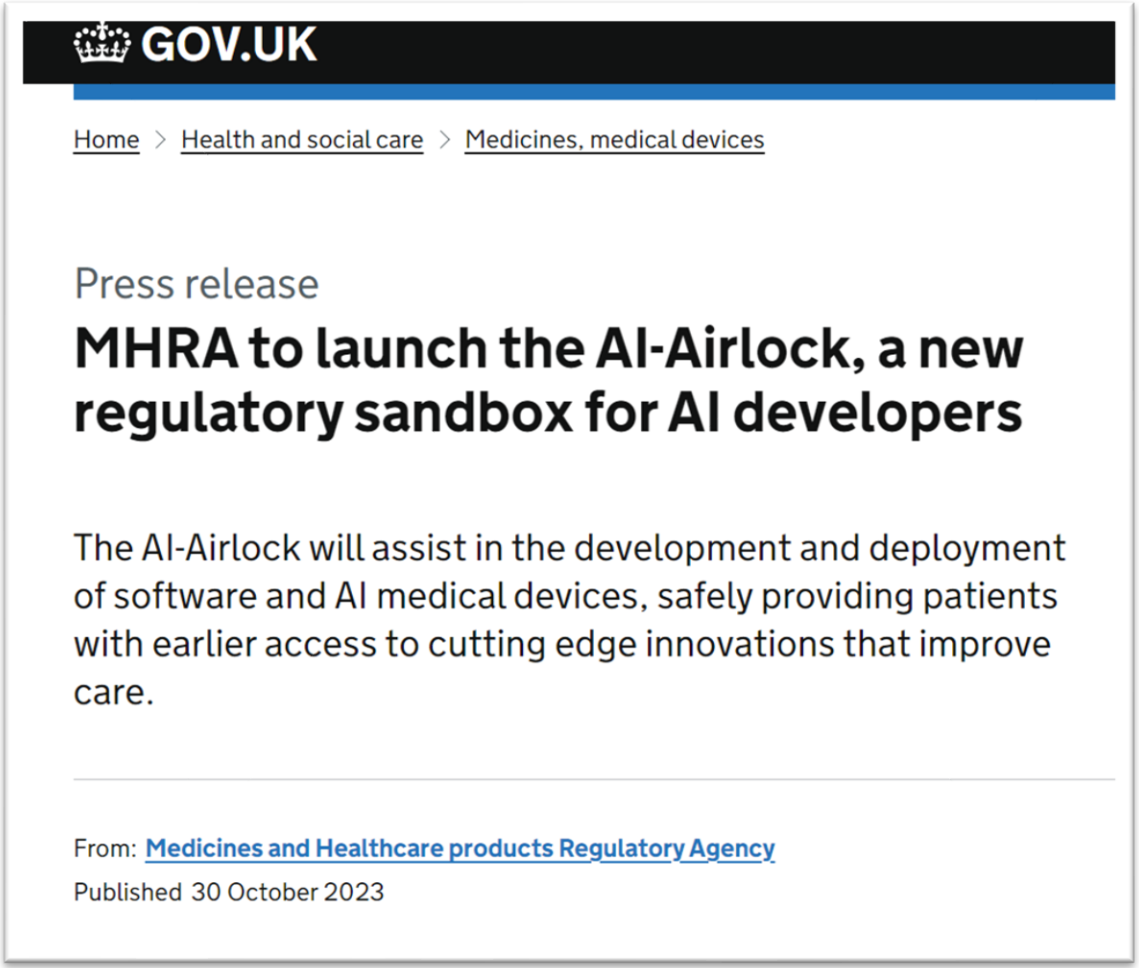
3

Playground for technical testing of a regulatory tool
An application testing environment that isolates untested code changes and experimentation from the production environment.

E.g., EUDAMED playground


Market Authorization
CE, UKCA, NMPA, 510(k),
de novo, PMA, ...
Market Access
procurement, reimbursement
health technology assessment
1
Framework for negotiated rulemaking
2
Regulatory advisory service
3
Playground for technical testing of a regulatory tool
FDA's Pre Cert & Case for Quality
Health Canada for ATPs
MHRA's Airlock
Singapore's LEAP
national and regional sandboxes to adapt clinical workflow and healthcare financing and reimbursement rules
FDA's Pre-Sub, Breakthrough Device Program, STeP & TPLC advisory program
MHRA's MAAS
EU's AI Act & TEFs, MD expert panels EMA's PRIME & cutting-edge dev.
EUDAMED playground

The UK Medicines and Healthcare products Regulatory Agency (MHRA) announced it is taking forward its new ‘regulatory sandbox’, the AI-Airlock, to provide a regulator-monitored virtual area for developers to generate robust evidence for their advanced technologies.



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Press release

MHRA to launch the AI-Airlock, a new regulatory sandbox for AI developers

The AI-Airlock will assist in the development and deployment of software and AI medical devices, safely providing patients with earlier access to cutting edge innovations that improve care.

From: Medicines and Healthcare products Regulatory Agency

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Goals

1

Framework for negotiated rulemaking

Market Authorization

CE, UKCA, NMPA, 510(k), de novo, PMA, ...

Market Access

procurement, reimbursement health technology assessment

Allow legislators to

1. increase their understanding of the technology, the business models, risks, and incentives
2. determine whether existing legislation is fit for purpose and/or inform legislative initiatives (drafting or reviewing legislation) and enhance the regulatory system in view of better health outcomes, improved patient experience, improved user experience, lower cost of care, and helping people to take better care of their health at every stage of life
3. avoid overengineering/overfitting legislation to one specific technology
4. Issue opinions and recommendations for the drafting of legislative guidance, international standards, technical specifications and identify standards for potential harmonization or recognition

Allow health institutions, insurers, and manufacturers to

1. experiment with the new technology and its role in clinical practice
2. gain insight into clinical evidence or health economics
3. gain trust
4. adapt the technology (safer/better utility/performance), care processes, financing, and reimbursement rules
5. reduce time to market/help patient

Market Authorization
CE, UKCA, NMPA, 510(k),
de novo, PMA, ...

Market Access
procurement, reimbursement
health technology assessment

Desired Operating Parameters

1

Framework for negotiated rulemaking

- be voluntary
- be limited in time and space to avoid a two-tiered regulatory system
- provide harmonized/standardized eligibility criteria to avoid regulatory arbitrage and forum shopping
- encourage participation by
  1. providing a waiver from specific legal provisions or compliance processes or find other means to avoid inadvertently increasing the regulatory burden or financially penalizing the participants
  2. providing incentives, such as access to qualitative data for training, tuning, and testing purposes, supervisory discretion from traditional market authorization and/or market access processes, reduced fees, etcetera
- start with a commitment (e.g., letter of intent) in which all stakeholders engage equally and involve predetermined proof points
- appropriately staffed (they are resource intensive) with sustainable funding

- ensure conformity assessments are accepted by notified bodies, e.g., by translating technical aspects into harmonized standards or guidances

- target scalability across healthcare and economic sustainability for all stakeholders by avoiding costly bespoke customization and solutions