EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Workshop on quality support to early access approaches (PRIME & Breakthrough)

Welcome

Enrica Alteri, EMA, Head of Human Medicines Research and Development Support Division

Guido Rasi at EMA's workshop on regulatory science:

"Breakthrough in science can considerably improve the lives of many patients across Europe and we need to be prepared with the right tools to assess and make these breakthroughs available for them"

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Workshop on quality support to early access approaches (PRIME & Breakthrough)

Setting the scene for today

Sol Ruiz, Keith Pugh & Veronika Jekerle

Enable faster development and approval in areas of unmet medical need/ major public health need **without compromising quality**, safety and efficacy

…. to achieve a robust manufacturing process and adequate product control at time of MAA approval of the medicine

Focus for today:

Challenges

Time

Innovation & complexity

Global projects

& solutions

Industry:

share experience
highlight concerns

Case studies

shape future agenda

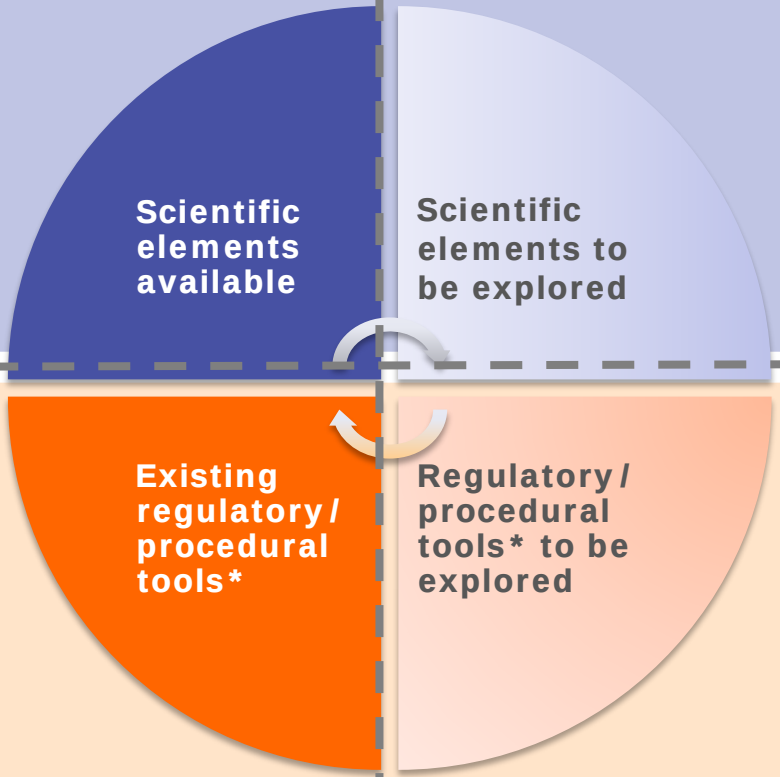
Regulators:

listen
understand

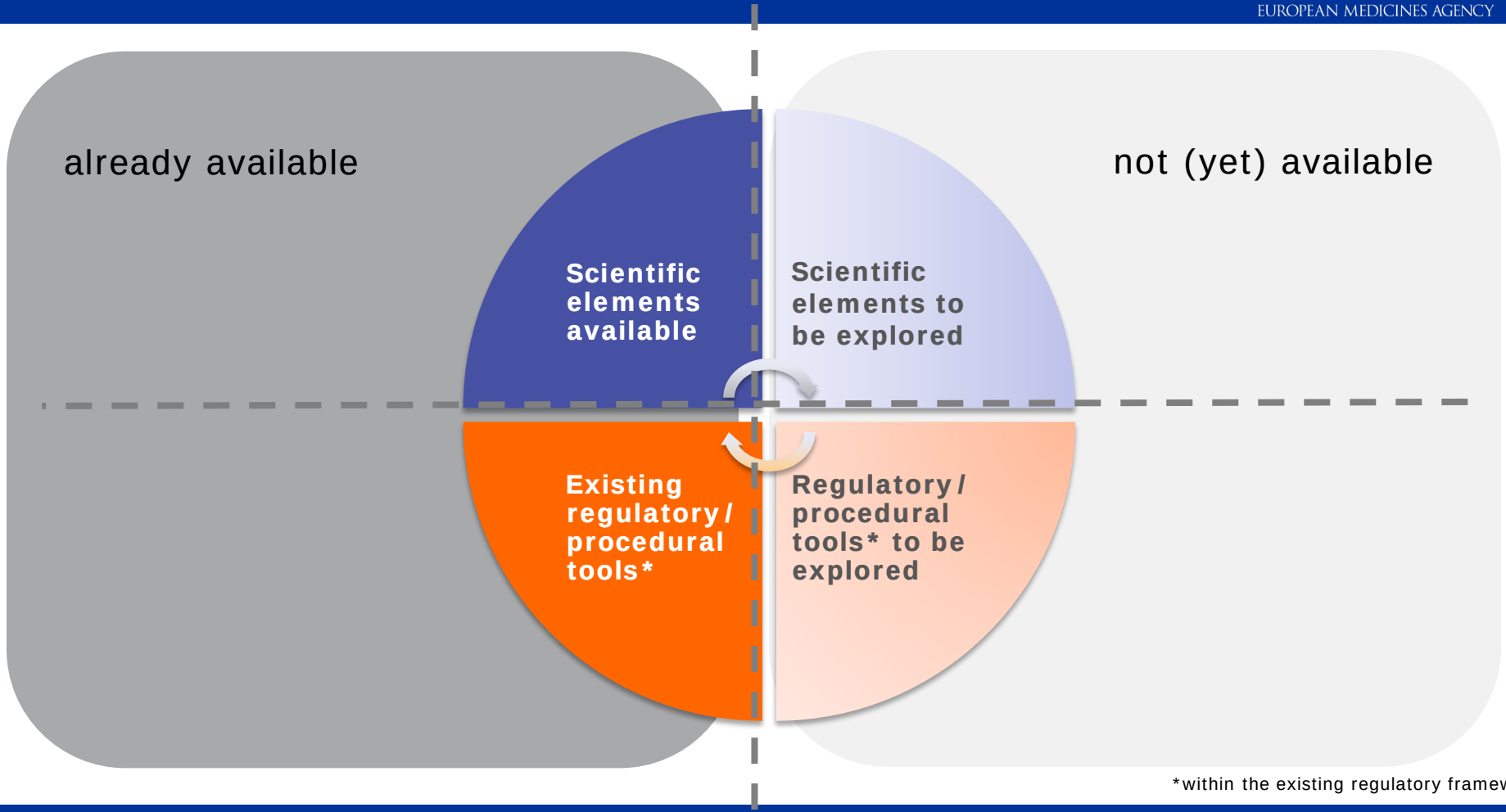
support
explore flexibility
explore harmonisation
plan

Scientific elements

Regulatory/ procedural tools

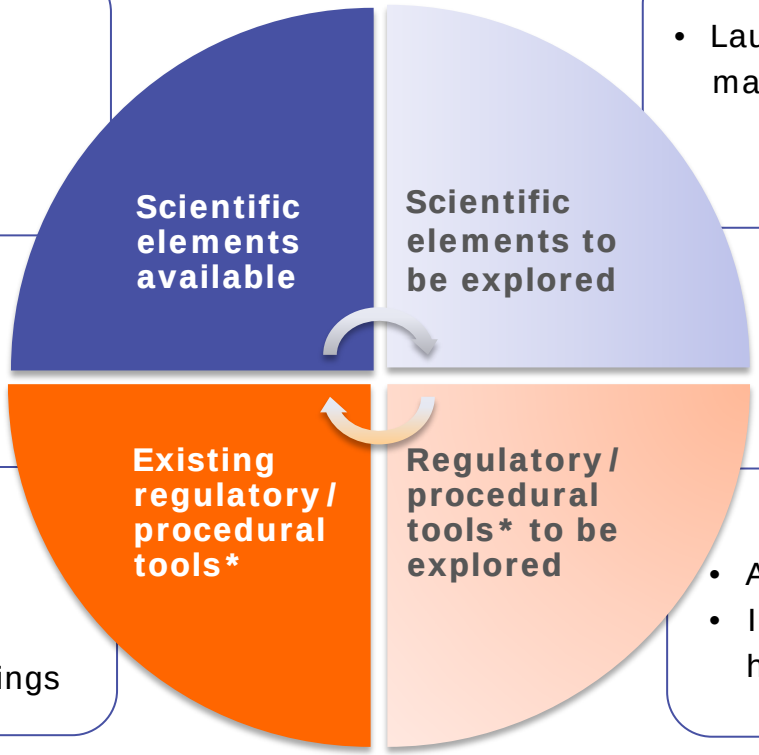


*within the existing regulatory framework



*within the existing regulatory framework

- Extend the shelf-life during review
- Concurrent PV
- Prior knowledge



- Launch from the clinical manufacturing site

- PACMP
- Recommendations
- Scientific advice
- PRIME kick-off meetings

- Annual reporting
- International harmonisation

*within the existing regulatory framework

EMA-FDA harmonisation

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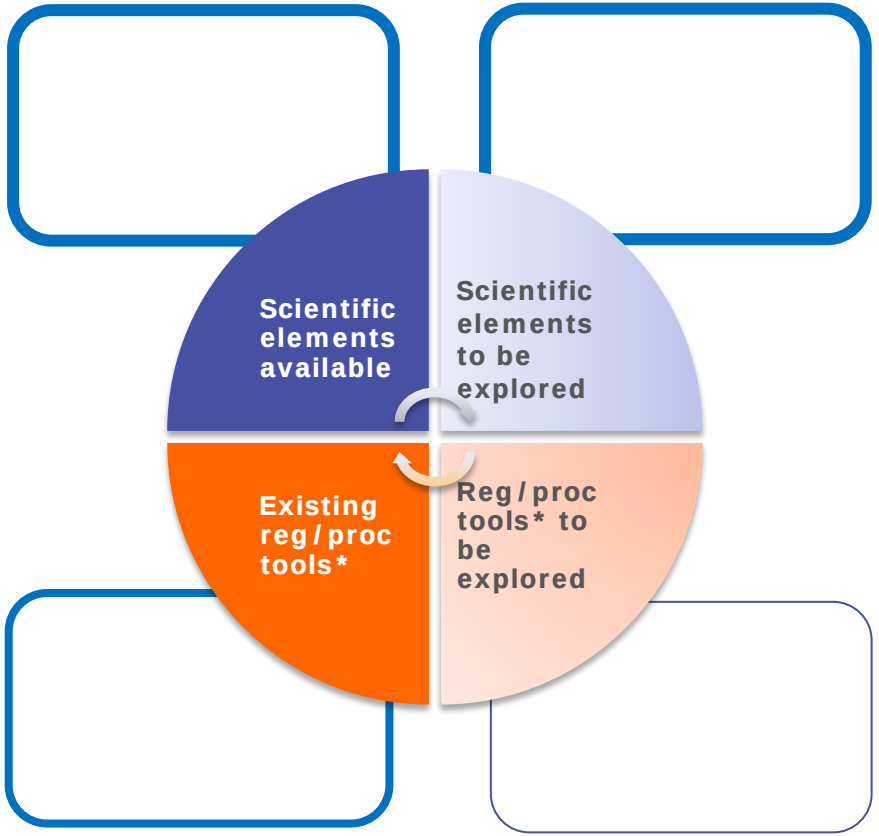
FDA



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