EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA support to innovative developers

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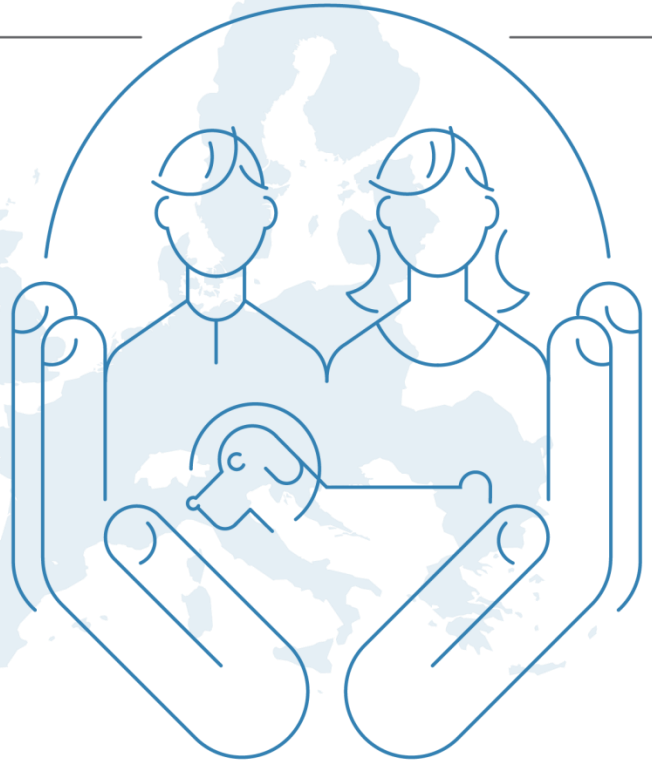
Disclaimer

The presenter does not have any conflict of interest.

What does EMA do?

Protect human and animal health

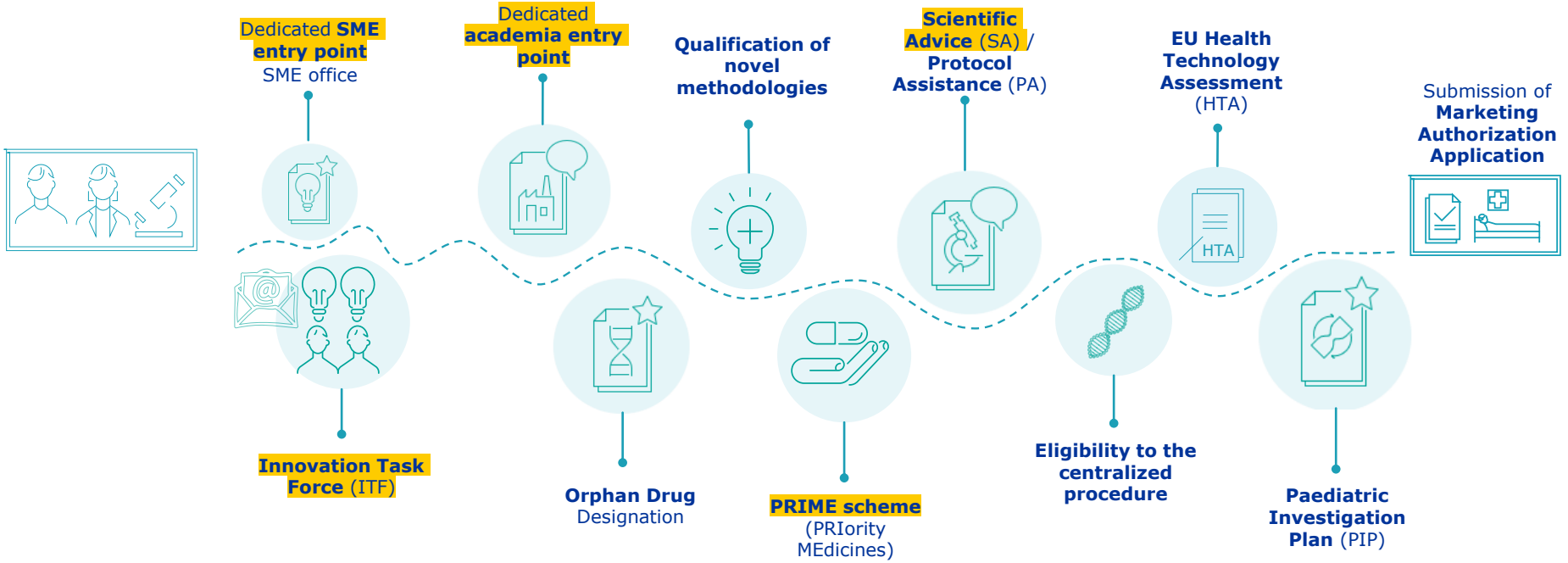
- Facilitate development and access to medicines
- Evaluate applications for marketing authorisation
- Monitor the safety of medicines across their life cycle
- Provide reliable information on human and veterinary medicines to patients and healthcare professionals



The European Medicines Regulatory Network

- ~50 national regulatory authorities
- European Medicines Agency
- European Commission

EMA interactions along the medicine development



Innovation Task Force (ITF)

Multidisciplinary platform

for preparatory dialogue and orientation on

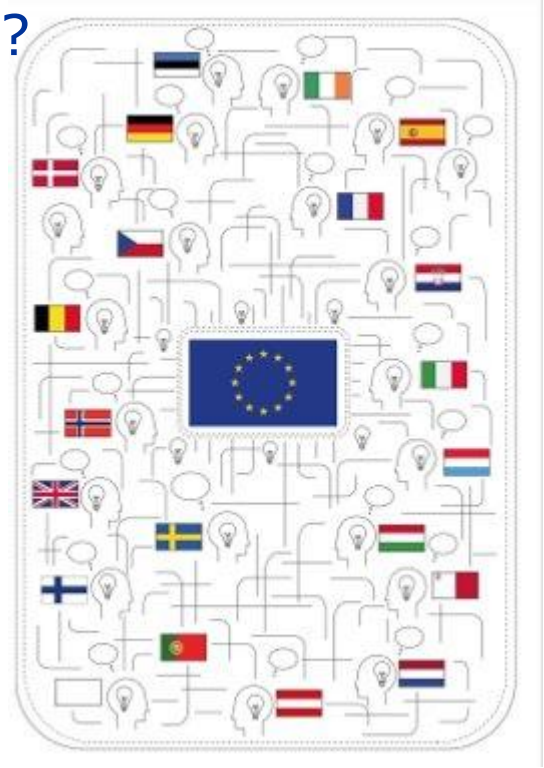
innovative methods, technologies and medicines

- Support **innovative** drug development
- **Early informal** dialogue with opinion leaders (can be requested at any stage of develop.)
- 1,5-hour discussion – Free of charge
- Brainstorming "style" on innovation in areas without existing guidance

ITF secretariat@ema.europa.eu

Who are the experts joining the ITF meetings?

- ITF team
- EMA colleagues
- Experts from the EU network (EMA committees, EMA working parties, EU-IN…)
- Other regulators as discussed with applicants (FDA, Swissmedic…)



Examples of developments

Emerging therapies

- ATMPs
- Nano-medicines

Emerging Technologies

- Digital technologies
- AI-driven manufacturing

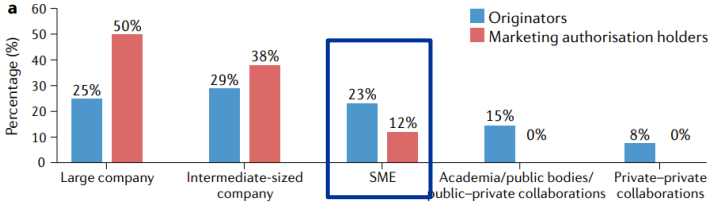
Emerging methods

- 3Rs
- Clinical Trial methodology

SME office

- Assignment and renewal of SME status
- Regulatory support (e.g., EMA procedures)
- Fee incentives
- Translation assistance for product information
- Training and awareness (info days & SME newsletters)

SMEs are a source of innovation



Provansal *et al.*, Nat Rev Drug Discov, 2022

SME@ema.europa.eu

SME Helpline :+31 (0)88 781 8787

Engagement with academia

Objectives

- Promote translation of academic research into novel methodologies and medicines
- Collaborate on areas of research on regulatory science
  - **Dedicated entry point** for Academia**:** academia@ema.europa.eu
  - **Financial incentives**: *protocol assistance* free of charge for developers of orphan medicines, scientific advice free of charge for products with *PRIME status*
  - EMA pilot offers **enhanced support to academic and non-profit developers of ATMPs**: ATMPpilot@ema.europa.eu

Scientific Advice (SA) and protocol assistance

- Supports the development of high-quality, effective & safe medicines
- Can be provided on any scientific question (quality, manufacturing, non-clinical development, clinical trials)
- New method or biomarker (e.g. registries): *qualification of novel methodology*

Special fee incentives:

- 90% fee reduction for SA to SMEs
- Protocol assistance **free-of-charge** to SMEs & academic developers

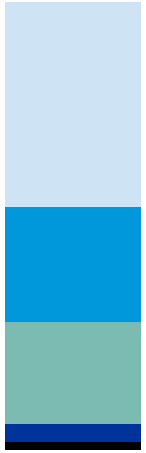
scientific.advice@ema.europa.eu

PRIME (PRIority MEdicines)

- Set-up in March 2016
- Enhanced support for drugs that could address an unmet medical need

Key features:

- Early assessment team appointment
- "Kick-off" meeting with multidisciplinary expertise from EU network
- Scientific advice at key development milestones
- Total fee exemption for SA to SME and academic applicants from the European Economic Area



120 **Requests granted**
By type of medicines:

56 **Advanced therapies**

29 **Biologicals**

27 **Chemicals**

7 **Immunologicals**

1 **Radiopharmacological**

27 **PRIME medicines received a Marketing Authorization**

78% Orphan Medicines

1 in 3 Applications have been submitted by SMEs

PRIME@ema.europa.eu

Conclusion

EUROPEAN MEDICINES AGENCY

Europe has world class academic- and industry-driven R&D, including on advanced therapies

European innovation ecosystem is well-positioned generating ideas for novel health care solutions

The challenge is the translation into tangible impactful products

The EU supports the translation of innovations and ideas into health care products

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Further information

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