EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

The role of EMA in promoting innovation and supporting developers

EMA EU-IN workshop with Academia

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An agency of the European Union

Vision

*EMA needs to take a **new role at the crossroads between science and national healthcare systems.** In order to promote public health in the current environment, the Agency can no longer be just a gateway between those two worlds.*

*Within its mission of protecting human and animal health, EMA needs to become a **catalyst**, an enabler for **science to be translated** into **patient-centred** healthcare and fit in the **reality of healthcare systems**.*

What we must do

- Embrace science, technology and communication tools which are changing society at fast pace: engage in collaborative EU and international Horizon Scanning
- Contribute regulatory science in shaping EU Research and Health policies to further develop an internationally attractive eco-system in Europe
- Engage in collaboration with players key for developing research tools, medicines, health technologies and their implementation in public health
- Strategically recruit and manage best expertise, streamline regulatory pathways and catalyse synergies for medicines development and delivery to patients

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Shaping regulatory science to 2025

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News 17/10/2018

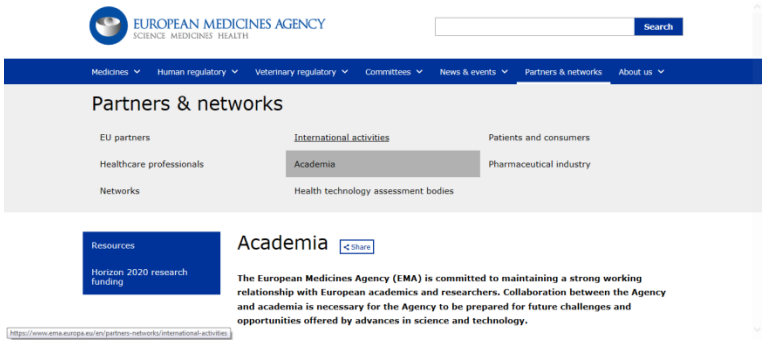
EMA is hosting a workshop on Wednesday, 24 October to gather insight from stakeholders on the key areas in human medicines to be covered in its 'Regulatory Science Strategy to 2025', a proposed new high-level plan for advancing its engagement with regulatory science.

The workshop will offer an opportunity to reflect on the scientific and technological advances in the pharmaceutical arena, the challenges that the Agency's scientific committees and working parties will face in the future and to look at initial proposals to address them. It will also highlight areas relevant to various stakeholder groups in advance of a six-month public consultation on the proposed strategy to be launched in December 2018.

"The pace of innovation has accelerated dramatically in recent years and regulators need to be ready to support the development of increasingly complex medicines that more and more deliver healthcare solutions by converging different technologies to promote and protect human and animal health," said Guido Rasi

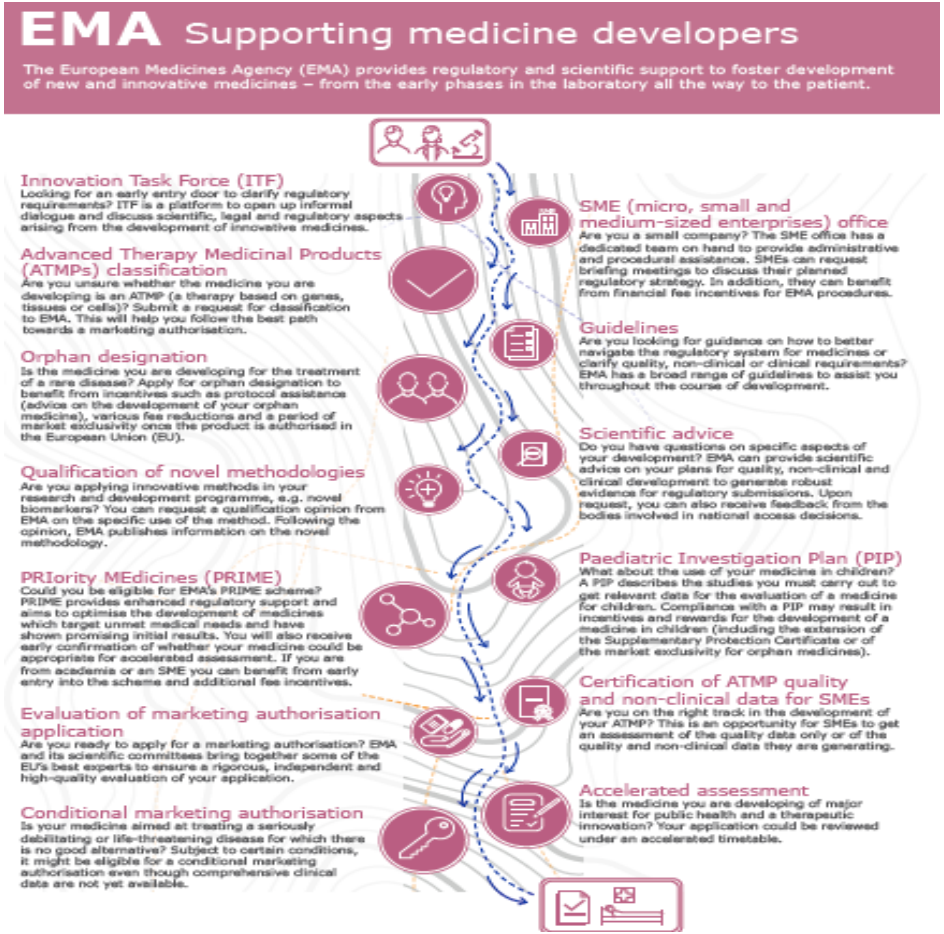
https://www.ema.europa.eu/

Partners: framework for collaboration with Academia



https://www.ema.europa.eu/en/partners-networks/academia

- Raise awareness of EMA's role within the European medicines regulatory network;
- Promote and further develop regulatory support for translating academic research into novel methodologies and medicines;
- Ensure that the best scientific expertise and academic research is available to inform regulatory decision-making;
- **Collaborate** on areas of research on regulatory science, such as novel approaches, endpoints and methodologies.



- ⇨ Medicines development multifaceted
- ⇨ A complex endeavour
- ⇨ Need for best + novel expertise
- ⇨ Many opportunities = many tools needed

Collaboration in many ways

Scientific advice and protocol assistance

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The European Medicines Agency (EMA) can give scientific advice and protocol assistance to medicine developers. For human medicines, scientific advice and protocol assistance are given by the Committee for Medicinal Products for Human Use (CHMP) on the recommendation of the Scientific Advice Working Party (SAWP).

Qualification of novel methodologies for medicine development

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The European Medicines Agency offers scientific advice to support the qualification of innovative development methods for a specific intended use in the context of research and development into pharmaceuticals.

The advice is given by the Committee for Medicinal Products for Human Use (CHMP) on the basis of recommendations by the Scientific Advice Working Party (SAWP). This qualification process leads to a CHMP **qualification opinion** or CHMP **qualification advice**.

CHMP qualification opinions

The CHMP can issue an opinion on the **acceptability of a specific use of a method**, such as the use of a novel methodology or an imaging method in the context of research and development. The metho can apply to non-clinical or to clinical studies, such as the use of a novel biomarker.

The opinion is based on the assessment of data submitted to the Agency.

Before final adoption of qualification opinion, the CHMP makes its evaluation open for **public consultation** by the scientific community. This ensures that the CHMP shares information, as agreed with the applicant, and is open to scientific scrutiny and discussion.

PRIME is a scheme launched by the European Medicines Agency (EMA) to enhance support for the development of medicines that target an unmet medical need. This voluntary scheme is based on enhanced interaction and early dialogue with developers of promising medicines, to optimise development plans and speed up evaluation so these medicines can reach patients earlier.

Through PRIME, the Agency offers early and proactive support to medicine developers to optimise the generation of robust data on a medicine's benefits and risks and enable accelerated assessment of medicines applications.

This will help patients to benefit as early as possible from therapies that may significantly improve their quality of life.

Accelerated assessment

PRIME builds on the existing regulatory framework and tools already available such as scientific advice and accelerated assessment. This means that developers of a medicine that benefitted from PRIME can expect to be eligible for accelerated assessment at the time of application for a marketing authorisation.

Related content

- Support for early access
- Two years of PRIME (7/5/2018)
- First anniversary of PRIME: experience so far (19/5/2017)
- Launch of PRIME – Paving the way for promising medicines for patients (07/03/2016)

Report: PRIME: a two-year overview

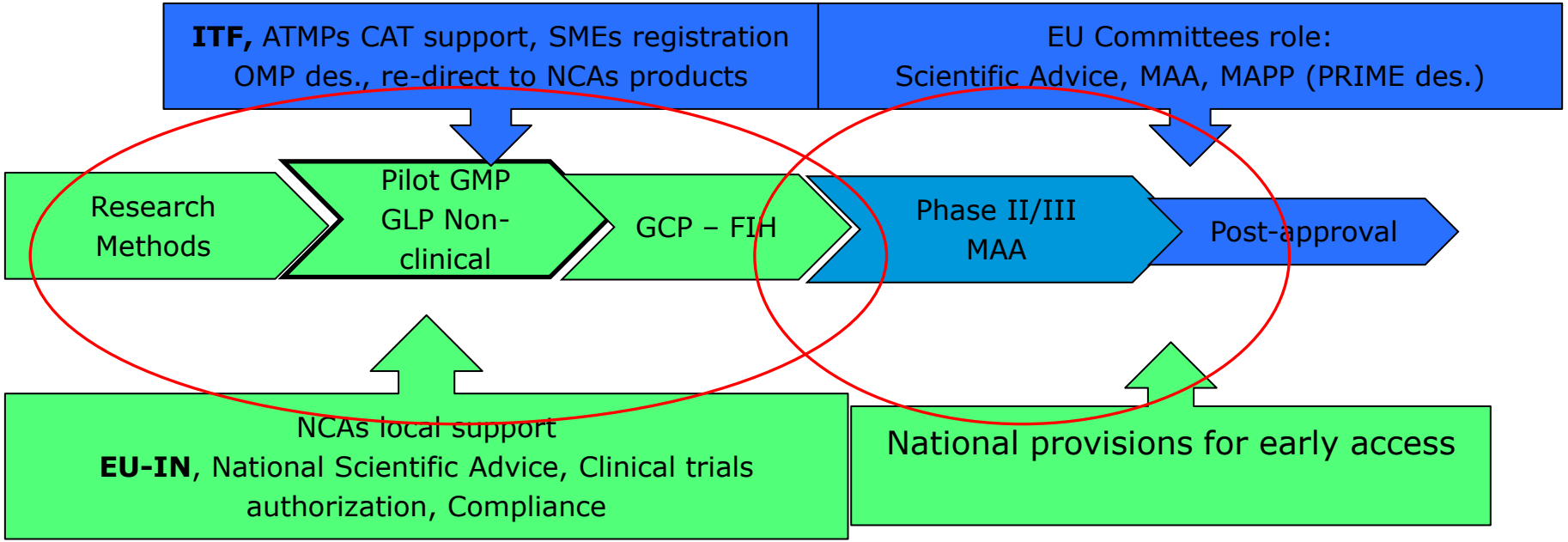
EU Innovation Network

Innovation offices in national regulatory agencies have been working informally with the EMA's Innovation Task Force (ITF) on matters relating to emerging therapies and technologies since 2011. In 2015, EMA and the EU national competent authorities (NCAs) strengthened their collaboration to **support medicine innovation and early development of new medicines** in the EU by establishing the EU innovation network.

EMA and the HMAs adopted the **mandate** of the EU-Innovation Network in October 2016:

- Mandate of the European Innovation Network

EU-IN for the EU seamless support to Innovation



Thanks for your attention, engagement and questions

Further information

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