

The role of EMA in promoting innovation and supporting developers

EMA EU-IN workshop with Academia

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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 patientcentred 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



Horizon Scanning and Regulatory science: consult and prioritise collectively goals and recommendations



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

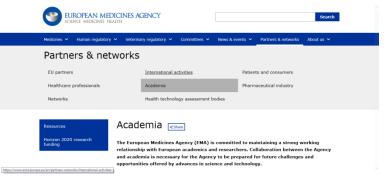
support the development of increasingly complex medicines that more and more deliver healthcare solutions

pa.eu/

Description different technologies to promote and protect human and animal health," said Guido Pasi



Partners: framework for collaboration with Academia



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

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



EMA supporting medicine developers



EMA Supporting medicine developers

The European Medicines Agency (EMA) provides regulatory and scientific support to foster development of new and innovative medicines – from the early phases in the laboratory all the way to the patient.

Innovation Task Force (ITF)

Locking for an early entry door to derify regulatory requirements? ITF is a platform to open up informal dialogue and discuss scientific, legal and regulatory aspects arising from the development of innovative medicines.

Advanced Therapy Medicinal Products (ATMPs) classification

Are you unsure whether the medicine you are developing is an ATMP (a therapy based on genes, tissues or cells)? Submit a request for dessification to EMA. This will help you follow the best path towards a marketing authorisation.

Orphan designation

Is the medicine you are developing for the treatment of a nere disease? Apply for orphan designation to benefit from incentives such as protocol assistance (advise on the development of your orphan medicina), various fee reductions and a period of the Buropean Union (EU). Product is authorised in the Buropean Union (EU).

Qualification of novel methodologies

Are you applying innovative methods in your mesench and development programme, s.g., novel biomarkers? You can request a qualification opinion from EMA on the specific use of the method. Following the opinion, EMA publishes information on the novel methodology.

PRIority MEdicines (PRIME)

Could you be eligible for EMA's PRIME scheme? PRIME provides enhanced regulatory support and aims to optimise the development of medicines which target unmet medical needs end have shown promising initial results. You will also receive early confirmation of whether your medicine could be from academic or an SME you can benefit from early entry into the scheme and additional fee incentives.

Evaluation of marketing authorisation application

Are you ready to apply for a marketing authorisation? BMA and its scientific committees bring together some of the EU's best experts to ensure a rigorous, independent and high-quality evaluation of your application.

Conditional marketing authorisation Is your medicine aimed at treating a seriously

debilitating or life-threatening disease for which there is no good alternative? Subject to certain conditions, it might be eligible for a conditional marketing authorisation swen though comprehensive clinical data are not yet available.

SME (micro, small and medium-sized enterprises) office

Are you a small company? The SME office has a desicated beam on hand to provide administrative and procedural assistance. SMEs can request briefing meetings to discuss their planned regulatory strategy. In addition, they can benefit from financial fee incentives for EPA procedures.

Guidelines

Are you looking for guidence on how to better navigate the regulatory system for medicines or clarify quality, non-clinical or clinical requirements? EMA has a broad range of guidelines to assist you throughout the course of development.

Scientific advice

Do you have questions on specific espects of your development? EMA can provide scientific advice on your plans for quality, non-clinical and clinical development to generate robust evidence for regulatory submissions. Upon request, you can also receive feedback from the bodies involved in national access decisions.

Paediatric Investigation Plan (PIP)

What about the use of your medicine in children? A PIP discribes the studies you must carry out to get relevant date for the evaluation of a medicine for children. Compliance with a PIP may result in incentives and rewards for the development of a medicine in children (including the extension of the Supplementary Protection Cartificate or of the market exclusivity for orphan medicines).

Certification of ATMP quality

and non-clinical data for SMEs
Are you on the right track in the development of
your ATMP? This is an opportunity for SMEs to get
an assessment of the quality data only or of the
quality and non-clinical data they are generating.

Accelerated assessment

Is the medicine you are developing of major interest for public health and a therapeutic innovation? Your application could be reviewed under an accelerated timetable.



- 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 cshare

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 method 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 <u>CHMP</u> makes its evaluation open for **public consultation** by the scientific community. This ensures that the <u>CHMP</u> shares information, as agreed with the applicant, and is open to scientific scrutiny and discussion.

PRIME - PRIORITY MEDICINES

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 <u>accelerated assessment</u> at the time of application for a <u>marketing authorisation</u>.

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



EU Innovation Network

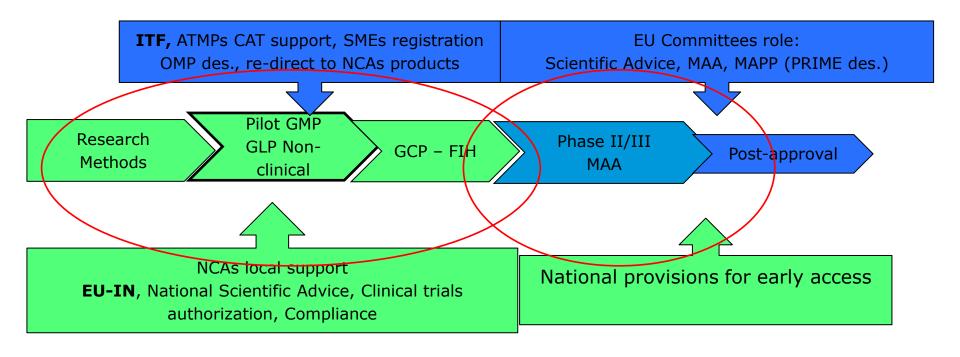
Innovation offices in national regulatory agencies have been working informally with the EMA's Innovation Task Force (ITF) on matters relating to emerging therapies and technologies since 2011. In 2015, EMA and the EU national competent authorities (NCAs) strengthened their collaboration to support medicine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