The Evaluation of third mission of Universities and Public Research Organisations

ANVUR Workshop – 4th May, 2015 Rome - Italy

The production of social cultural and educational public good

The European Medicines Agency and the Innovation Task Force

Presented by Marisa Papaluca on 4th May 2015
Senior Scientific Advisor – European Medicines Agency
European Medicines Network and the European Medicines Agency (EMA)

EMA core business: foster network’s **regulatory science to**
• support innovation in R&D for the development of better medicines
• develop robust methods to support the **lifecycle** medicines’ evaluation

Science-based **peer review network system**
• Experts from 28 National authorities
• Stakeholders and civil society
• Global dimension
EMA Centralised Procedure

- Single European scientific opinion
- 1 authorization for the whole EU
- 1 name
- 1 common Product information in 22 languages + IS/NO
- Transparent system (e.g. EPAR)
- Access to 500 million users
- World-wide impact
Academia/PROs and origin of new medicines

Clinical Development of Advanced Therapy Medicinal Products in Europe: Evidence That Regulators Must Be Proactive

Romaldas Maciulaitis\textsuperscript{1,2}, Lucia D’Apote\textsuperscript{3}, Andrew Buchanan\textsuperscript{1}, Laura Pioppo\textsuperscript{4,5} and Christian K Schneider\textsuperscript{1,5,6}

doi:10.1038/nrt.2012.11
Cultural dimension: from excellence to public good

Innovate and become attractive platforms for both prospective young brains and industrial/cultural enterprises: looking in to societal needs

Partnership with civil society in a collective effort to translate scientific excellence in public benefits and services
Local support to third mission: new specialized competences

• Communication channels and media for valorization of “joint success stories” to gain public trust

• Effective societal engagement in the territory: from conferences, to interactive platforms, resources exchange and services

• Administrative support for partnerships/Shared ownerships: Grant applications (national/international), contracts, coordination and administration, patents, PPPs, spin-offs, CROs
Third mission: some success features (ctd)

- Regulatory science support (e.g. health products)
- National Agencies Innovation offices: the window to Europe
- EMA Innovation Task Force
Regulatory Science and Medicines lifecycle

Personalised medicines development building blocks

Science, technology, methods

Development

Approval

Post-approval use and development
Regulatory Science support: seeing through the eye of the innovators

Issues:
- Daunting dialogue with regulators
- Small start-ups,
- Academic/PROs regulatory capacity

Solutions:
- Early regulatory science support from ‘Innovation Task Force’ (safe harbor)
The **Innovation Task Force (ITF)** is a multidisciplinary group that includes scientific, regulatory and legal competences, set up to ensure Agency-wide coordination in the areas of interest and to provide a forum for early dialogue with applicants.

- **Mandate of the Innovation Task Force**
- **Medicines and emerging science**

**Briefing meetings**

The scope of the briefing meetings covers regulatory, technical and scientific issues arising from innovative medicines development, new technologies and borderline products.

The ITF, within 60 days of receipt of a valid request from an applicant, arranges free-of-charge briefing meetings to facilitate the informal exchange of information and the provision of guidance early in the development process.

The scientific discussions are led by experts from the Agency network, working parties and committees, where the best available scientific expertise is represented.

Briefing meetings are meant to complement and reinforce existing formal regulatory procedures (e.g. ATMP classification, ATMP certification, designation of orphan medicinal products, CHMP scientific advice, etc.).

- **Standard Operating Procedure for organisation of briefing meetings**
Regulatory Science support: INNOVATION TASK FORCE

Easy Access: apply via website www.ema.europa.eu

Voluntary and free of charge

F2F multidisciplinary meeting reserved to Innovators (early stage)

Reply within 14 days

Briefing meeting/TC within 2 months

Output in writing
Regulatory Science support:

2012 → 2014

50% products
50% biomarkers/methods/models
Build on knowledge, regulatory science and experience to focus on public good outputs (from new methods definition to new products)

Support early analysis of potential deliverables of innovative and “added value” projects

Impact on both stakeholders’ and investors’ interest

Plan for formal interaction in scientific advice and methods “qualification”
Regulatory Science support:

Scientific advice

Success → Failure ←
Regulatory Science support

Methods/biomarkers Qualification and products R&D Scientific Advice

Qualification of novel methodologies for medicine development

The 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 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.

CHMP qualification advice

The CHMP offers advice on protocols and methods that are intended to develop a novel method with the aim of moving...
Regulatory Science support

**SCIENTIFIC ADVICE**

Formal acceptability of Product data/method for decision making

Platform for structured public engagement:

- Health Technology Assessment bodies, Health Care Professionals, Patients’ organisation
- International scientific advice with FDA
- Adaptive Pathways to patients’ access

and more...
De-risk innovation
Come early - Come often
Share knowledge and experience
Seek guidance in development
Avoid waste
Become attractive to investors and industry

Develop and validate new methods
Bring good products to patients
Thanks you for your attention

Further information

Marisa.papaluca@ema.europa.eu

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000 Facsimile +44 (0)20 3660 5555
Send a question via our website www.ema.europa.eu/contact

Follow us on @EMA_News