EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Framework of collaboration with Academia

Discussion session

Objectives of the discussion

- Gather your input on key elements that should underpin the relationship between learned societies and regulators
- Identify unmet needs in your own fields
- Support development of the EMA framework of collaboration with Academia
- …

Points for discussion

Regulatory Science (the science of developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of regulated medicinal products)

- Is the current **collaboration meaningful?**
- Do you feel that **unmet medical needs and scientific progress** in your own fields are adequately addressed in EMA's guideline development? Could we do better?
- What would you suggest to stimulate **translation of scientific advance into drug development and drug utilisation**? Is there an 'appetite' for regulatory science?
- Is there a need for **centres of excellence** to build up regulatory science competences?

Points for discussion

Drug development and pre-authorisation

- Pharmaceutical legislation already provides certain levels of **incentives** (e.g. paediatrics, advanced therapies, orphans). Could EMA further support the **practical implementation** of such incentives?

Examples:

  - 'Qualification Advice' - **advice on protocols and methods** that are intended to develop a novel method with the aim of moving towards qualification
  - **Research networks** as dialogue platforms (e.g. ENCePP; ENPR-EMA)
  - **Multi-stakeholder workshops/conferences** on specific topics

Points for discussion

Drug utilisation and post-authorisation

- What level of collaboration can be envisaged in relation to **post-authorisation safety and efficacy studies** (PASS/PAES)?
  - PASS: any study relating to an authorised medicinal product conducted with the aim of identifying, characterising or quantifying a safety hazard, confirming the safety profile of the medicinal product, or of measuring the effectiveness of risk-management measures.
  - PAES: studies conducted within the authorised therapeutic indication to complement available efficacy data in the light of well-reasoned scientific uncertainties on the evidence of benefits that could not be resolved prior to authorisation or were identified after authorisation.

- What type of collaboration could be developed in relation to **patient registries**?

Points for discussion

Communication/Awareness/Visibility

- What could EMA do to **reach out to academics?**

  (including wider ranges of disciplines and fields of expertise such as, e.g., tropical medicine; nanotechnology; adaptive pathways; modelling and simulation; risk communication; practice-based research)

- What communication channels should we use? Is there a need/added value to develop specific communication tools (e.g. newsletter)?
- What synergies could be explored with scientific/learned societies' journals?
- What would be your suggestions for **further collaboration**?
- …