Towards an EMA framework of collaboration with academia

Annual Meeting of the Alliance for Biomedical Research in Europe

Presented by Ivana Silva, 9 November 2016
Public Engagement Department
An Agency with a mission

Foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public health in the European Union
What do we do?

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

Protect human and animal health
Academia: an important source of innovation


An intricate regulatory environment

<table>
<thead>
<tr>
<th>Innovation task force (H&amp;V)</th>
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</thead>
<tbody>
<tr>
<td>Paediatric investigation plan (PIP) (H)</td>
</tr>
<tr>
<td>Scientific advice (H&amp;V)</td>
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<tr>
<td>Qualification of novel methodologies (H)</td>
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<tr>
<td>Advanced therapy medicinal product classification (H)</td>
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<tr>
<td>Regulatory and administrative assistance for small- and medium-sized enterprises (H&amp;V)</td>
</tr>
<tr>
<td>Orphan designation (including protocol assistance, fee reductions, market exclusivity) (H)</td>
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Supporting research and innovation of medicines
Academia and regulators are brought together

- **European Council conclusions on innovation for the benefit of patients** (1-12-2014): “...in order to stimulate development, there is a need to facilitate the translation of scientific advance into innovative medicinal products that meet regulatory standards”.

- **EU Medicines Agencies Network strategy to 2020** “…support for patient focused innovation and contribute to a vibrant life science sector in Europe.”

- **European Medicine Agency work plan 2016-2017** “...the Agency will support a strengthening of the collaboration and integration across the network and with academia...”

- **Horizon 2020 framework programme**: Health, demographic change and well-being, work programme 2016-2017 “…Engagement with regulators and consideration of the regulatory framework issues are highly recommended.”
EU Regulators and support to innovation

“EMA wants to move to a new level of collaboration with academia. Science is progressing fast and we see an unprecedented level of complexity in the development and evaluation of new medicine.

**Academia play an important role in helping the EU medicines regulatory network** to keep abreast of the opportunities and challenges brought by science and to have access to the right expertise to evaluate these innovative medicines.

Interaction with EU regulators and a **better understanding of the regulatory environment** can help academia translate their discoveries into patient-focused medicines. I believe that **working more closely together** will bring great **benefits to public health**”. Guido Rasi, EMA Executive Director

BioMed Alliance, 9 November 2016
Key Elements of Collaboration

- Motivation
- Communication
- Problem solving
- Collaboration
- Support
- Diversity
- Sharing
Structuring and strengthening collaboration

Expectation

Possible realities
Process leading to the EMA framework of collaboration with academia

- Decision to define and implement a framework of collaboration with academia
- Healthcare professionals’ working party (HCPWP) brainstorm Q2 2015
- Informal meetings with EU research infrastructures and academic stakeholders Q3-Q4 2015
- Launch of a public consultation: the survey Q1 2016
- First analysis survey results Q2 2016
- HCPWP Workshop on framework of collaboration with academia 15 June 2106
- Drafting of framework of collaboration with academia Q3-Q4 2016
- Adoption of the framework of collaboration with academia Expected Q4 2016
Consultation with academia via survey: objectives

• Take a snapshot of the current interaction between academia and regulators at European level, and collect needs and expectations (survey tool)

• Open a dialogue for laying the foundations of a robust framework of collaboration to:
  - support innovation in the biomedical field
  - underpin European translational medicine activities
  - enhance the development of regulatory science
  - attract leading expertise and enhance mutual understanding
Summary of profiling

- Respondents: 85% individuals (n=749) and 15% organisations (n=128)

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<thead>
<tr>
<th>Affiliation</th>
<th>Area of activity</th>
<th>Type of research</th>
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<tbody>
<tr>
<td>Public universities (n=381)</td>
<td>Medicine (n=717)</td>
<td>Clinical research (n=569)</td>
</tr>
<tr>
<td>University hospitals (n=257)</td>
<td>Pharmaceutical sciences (n=283)</td>
<td>Basic research (n=291)</td>
</tr>
<tr>
<td>General hospitals (n=133)</td>
<td>Biology (n=265)</td>
<td>Pre-clinical research (n=289)</td>
</tr>
<tr>
<td>Public research institutes (n=114)</td>
<td>Social sciences and Humanities (n=90)</td>
<td>Real-world research (n=245)</td>
</tr>
<tr>
<td>Private research institutes (n=51)</td>
<td>Chemistry (n=65)</td>
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Summary of Interaction with Regulators

- The **awareness of regulators’ role** and activities among academics has **space for improvement**
- **National Competent Authorities** (NCAs) represents a robust asset of interaction and contact with academics
- **EMA** should **strengthen its visibility** and outreach among academics
- Most of the **respondents provided their expert opinion** to regulatory activities
Overall summary of survey results

• The survey provided an **informative snapshot** of the current **interaction between academic** stakeholders and **EU regulatory bodies**

• It clearly identified a **need for enhancing awareness** of the role and activities of regulatory bodies among **academic** stakeholders

• It helped to **identify** the **key areas of collaboration** to be developed within the framework

• Over **900 written comments** identifying **strengths, weaknesses, opportunities, challenges** and further suggestions for enhancing collaboration

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Healthcare professionals’ working party (HCPWP) workshop on a framework of collaboration with academia: a further consultation step

**Workshop outcomes:**

- Consensus on the opportunities of **leveraging and enhancing existing activities** in the field of **education and training**, potentially combined with research endeavours;

- Call from academics to the regulators for **supporting independent research** (i.e. not industry driven) and proactively **indicate priorities and a strategic research agenda** in regulatory science;

- Consensus on the crucial importance of putting in place a **communication strategy** (in its tools and content) that will allow structured bidirectional exchanges.

- Links to [workshop webpage](#) and [report](#)
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The framework of collaboration

**Major objectives:**

- To raise awareness of the mandate and work of the Agency
- To promote and further develop the support on offer from the EMA
- To ensure that the best scientific expertise and research are channelled into the regulatory process

**Scope:**

- Public or private non-profit organisations/legal entities whose primary mission is to pursue/support/fund education and research at European level
- European research infrastructures, European learned/scientific societies, academies, federations and networks
  - Aiming at covering all fields related to the development, manufacturing, assessment, and use of medicines, including health communication and social sciences.
**EMA stakeholder relations management framework**

<table>
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<tr>
<th>Inform – to enable feedback</th>
<th>e.g. dedicated web pages, relevant news items, Q&amp;As, information days, information materials including videos and presentations</th>
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<tbody>
<tr>
<td>Consult – via written consultation</td>
<td>e.g. public consultation on policies or guidance, surveys</td>
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<tr>
<td>Consult and Involve – via direct interactions</td>
<td>e.g. multi-stakeholder meetings, workshops, conferences, public hearings, input into the development of regulatory guidelines and other regulatory procedures</td>
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<tr>
<td>Cooperate / participate – via direct interactions</td>
<td>e.g. participation to research projects, cooperation in activities of education and training, participation in scientific advisory groups and ad-hoc expert groups, cooperation with established EMA stakeholders and networks.</td>
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What have we achieved so far in the process

• Mapping of organisations
• Very stimulating bilaterals
• Coordination with EU Medicines Agencies
• Good exposure at key conferences
A journey has began! Shall we do it together?
Thank you for your attention

Further information

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