EMA Draft framework of collaboration with academia

ENCePP plenary meeting, 22 November 2016

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Head of Public Engagement Department
Communication and Stakeholders Division
Acknowledgments

- HCPWP Academia Topic Group – co-chairs Rosa Giuliani (ESMO) and Sergio Bonini (EMA)
- Internal EMA Academia Task Force
- Public Engagement Department
Academia: an important source of innovation


Why a framework of collaboration with academia

- 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.”
“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
Process leading to the framework of collaboration with academia

- EMA internal consultation on collaboration with academia
- HCPWP* brainstorming Q2 2015
- Informal meetings with EU research infrastructures and academic stakeholders Q3-Q4 2015
- Academia consultation: the survey Q1-Q2 2016
- HCPWP* Workshop on framework of collaboration with academia 15 June 2106
- Drafting of framework of collaboration with academia and consultations Q3-Q4 2016
- Adoption of the framework of collaboration with academia Expected end of Q4 2016

*Healthcare Professionals Working Party
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
  - To underpin European translational medicine activities
  - To enhance the development of regulatory science
  - To attract leading expertise and enhance mutual understanding
Online survey using SurveyMonkey®

Survey consisted of 3 parts: Profiling, Interaction with Regulators and Future Developments (12 questions in total; National Competent Authorities were consulted and their input incorporated into final version)

Launched 1 February 2016 – closed 18 April 2016

Published on EMA website and proactively disseminated through academic groups, learned societies and healthcare professional organisations

1016 respondents at survey closure (877 responses retained after data cleaning)
Profiling

- Profiling: 5 Questions
- Interaction with regulators: 5 questions
- Future developments: 2 questions
Respondents’ affiliation

- **As an individual**: 85%
- **On behalf of an organisation**: 15%

**Graphs showing affiliation types**:
- University, public
- University Hospital
- General Hospital
- Research institution, public
- Research institution, private non-profit
- Research Foundation
- Healthcare Professionals Association
- Learned/Scientific Society
- Research infrastructure
- University, private
Geographical distribution of respondents
## Summary of profiling

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

<table>
<thead>
<tr>
<th>Affiliation</th>
<th>Area of activity</th>
<th>Type of research</th>
</tr>
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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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</tbody>
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Interaction with regulators

Profiling
5 Questions

Interaction with regulators
5 questions

Future developments
2 questions
Awareness of the role and activities of regulatory bodies

Question: To what extent are you aware of the role and activities of regulators?

- To a great extent: 35%
- To a moderate extent: 39%
- To a little extent: 20%
- Not at all: 6%

Percentage Organisations:
- 48% (To a great extent)
- 35% (To a moderate extent)
- 13% (To a little extent)
- 4% (Not at all)

Percentage Individuals:
- 32% (To a great extent)
- 40% (To a moderate extent)
- 21% (To a little extent)
- 7% (Not at all)
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 the regulatory activities
Future developments

Profiling
5 Questions

Interaction with regulators
5 questions

Future developments
2 questions
What should be pursued for a closer collaboration between academia and regulators

- Targeted communication
- Knowledge exchange
- Regulatory awareness
- Regulatory education
- Staff exchange programmes
- Joint research
- Identification of regulatory challenges

- Strongly agree
- Somewhat agree
- Neither agree nor disagree
- Somewhat disagree
- Strongly disagree
Overall summary of survey results

- The survey provided an informative snapshot of the current interaction between academic stakeholders and 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
- [Survey report](#)
A further consultation step: Healthcare Professionals Working Party’s workshop on framework of collaboration with academia
A further consultation step: Healthcare Professionals Working Party’s workshop on framework of collaboration with academia

**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](#)
At this moment in time

- Decision to define and implement a framework of collaboration with academia
  - Q2 2015
- Internal EMA reflection and HCPWP brainstorming
  - Q2 2015
- Informal meetings with EU research infrastructures and academic stakeholders
  - Q3-Q4 2015
- Academia consultation: the survey
  - Q1-Q2 2016
- HCPWP Workshop on framework of collaboration with academia
  - 15 June 2016
- Drafting of framework of collaboration with academia and consultations
  - Q3-Q4 2016
- Adoption of the framework of collaboration with academia
  - Expected end of Q4 2016
Structure of the framework of collaboration
Structure of the framework of collaboration

- Rationale
- Scope of interaction
- Objectives
- Working methodology
- Action plan
Rationale: why do we need a framework of collaboration with academia?

- **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.”
Structure of the framework of collaboration

- Rationale
- Scope
- Objectives
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Scope of interaction

- Public or private higher education establishments awarding academic degrees, public or private non-profit organisations/legal entities whose primary mission is to pursue research, and international European interest organisations
- European research infrastructures
- Established European research consortia funded under public research programmes
- European learned/scientific societies, federations and networks

➢ Operating in all fields of research related to the development, manufacturing, assessment, and use of medicines, including health communication and social sciences.
Structure of the framework of collaboration

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Objectives

• To raise awareness of the mandate and work of the Agency within the European medicines regulatory network as a means to increase academia’s engagement and trust in the Agency’s activities

• To promote and further develop the support on offer from the EMA within the European medicines regulatory network to foster the translation of academic research into novel methodologies and medicinal products which meet the regulatory standards

• To ensure that the best scientific expertise and academic research are available to support timely and effectively evidence generation, regulatory advice and guidance, and decision making in regulatory processes
Structure of the framework of collaboration

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## Working Methodology

Based on 4 elements:

- EMA Stakeholder database
- EMA European Experts database
- Research and knowledge generation
- Communication & Multi-stakeholder dialogue

### EMA stakeholder relations management framework

<table>
<thead>
<tr>
<th>Element</th>
<th>Activities</th>
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<tbody>
<tr>
<td><strong>Inform</strong> – to enable feedback</td>
<td>e.g. dedicated web pages, relevant news items, Q&amp;As, information days, information materials including videos and presentations</td>
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<tr>
<td><strong>Consult</strong> – via written consultation</td>
<td>e.g. public consultation on policies or guidance, surveys</td>
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<td><strong>Consult and Involve</strong> – 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><strong>Cooperate / participate</strong> – 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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Structure of the framework of collaboration

- Rationale
- Scope of interaction
- Objectives
- Working methodology
- Action plan in development
Process leading to the framework of collaboration with academia: next step

1. Decision to define and implement a framework of collaboration with academia
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Thank you for your attention

Further information

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