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Stakeholders and Communication Division

Developing a framework of collaboration between the European Medicines Agency (EMA) and academia

Report of the workshop hosted by the Healthcare Professionals' Working Party (HCPWP)
15 June 2016, 11:00hrs to 16:30hrs – meeting room: 3E

1. Executive summary

During its June 2016 meeting, the Healthcare Professionals' Working Party (HCPWP) has hosted a workshop focused on the development of a framework of collaboration between EMA and academia.

In his opening statement Guido Rasi, EMA executive director, captured the rationale of this endeavour: "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 medicines. 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".

The major objectives of the workshop were to collectively review the *status quo*, present the different perspectives and expectations, and discuss the main pillars of the framework.

The workshop was also conceived as an opportunity of brainstorming and input gathering from academic stakeholders (see list of participants), and in this respect it fulfilled its promise. The exchange of information among organisers and participants and the lively, rich discussion that ensued were a confirmation that willingness and commitment are shared to successfully deliver a framework of collaboration that will allow the transition into an initial set of actions in the near future to identify roles, mandates, capabilities and capacity. The major outcomes of the discussion are summarised below:

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- 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, allowing timely and effective execution potentially underpinned by dedicated funding streams;
- consensus on the crucial importance of putting in place a communication strategy (in its tools and content) that will allow structured bidirectional exchanges.

The framework is set to be finalised and adopted by EMA Management Board by the end of 2016, with its initial implementation phase starting at the beginning of 2017.

2. Introduction and background

There is already a longstanding collaboration between regulators and academia as recognised in the European Medicines Agencies Network Strategy to 2020[1] that outlines joint key priorities and a high-level roadmap to achieve them. Indeed, academia is the source that provides the European medicines regulatory system with experts that bring their knowledge and experience to ensure that medicines are evaluated and monitored to the highest scientific standards (regulatory science[2]).

Advances in science are leading in an unprecedented pace to new medicines that are developed, manufactured, and used in completely new ways, where high degrees of complexity are often embedded. New technologies are emerging, and advanced therapies and personalised medicines will represent an increasing part of the healthcare armamentarium. Monitoring of products throughout their lifespan has never been more critical and new scientific and regulatory tools need developing along with the new therapeutic propositions. Information is needed on the benefit-risk balance of medicines throughout their lifecycle, particularly where early access has been granted and when the need to proactively gather and analyse data from the clinical use is even more important.

In order to ensure that scientific and technical advances efficiently contribute to address the need for patient-focused innovation, as recommended by the European Council[3], the Network Strategy to 2020 identifies key priorities which will need to be implemented in the coming years to 2020. As recently shown[4], academia is an important source of innovative medicines in the European Union. Consequently, opportunities for greater collaboration with academia need to be pursued in order to support the translation of scientific and technical innovation into medicinal products that meet regulatory standards, to approve them through adequate and up-to-date methodologies and to monitor their use during their entire life-cycle.

[1] EU Medicines Agencies Network Strategy to 2020
[2] For the purpose of the discussion regulatory science can be defined as a range of scientific disciplines that are applied to the quality, safety and efficacy assessment of medicinal products and that inform regulatory decision-making throughout the lifecycle of a medicine. It encompasses basic and applied bio-medicinal sciences, human sciences and social sciences, and contributes to the development of regulatory standards and tools.
[3] Council conclusions on innovation for the benefit of the patients, Council conclusion, Brussels, 1 December 2014
[4] Lincker H., Ziogas C., Carr M., Porta N., Eichler, H. G. Regulatory watch: Where do new medicines originate from in the EU? Nature Reviews Drug Discovery. 2014; 13(2): 92-93.

In this context, the European Medicines Agency has started an internal reflection and an external consultation process with the objective of informing the development of a framework of collaboration with academia. During its June 2016 meeting, the Healthcare Professionals' Working Party (HCPWP) has hosted a workshop to complement the consultation process to inform the definition of a framework of collaboration, based on robust foundations and effective constructive dialogue. The major objectives of the workshop were:

1. collectively review the *status quo*;
2. present the different perspectives and expectations;
3. discuss the main pillars of the framework.

Overall, the spirit of the workshop was to invite and capture further ideas and suggestions to complement the rich amount of input already obtained via the survey targeted to academia that the Agency run at the beginning of the year (a survey report will be published on the EMA website).

3. Building the foundations

Guido Rasi, EMA executive director, opened the morning session addressing the participants and setting the scene:

"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 medicines. 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".

The workshop agenda was built as to provide an overview of the current situation from the Agency's perspective and some academic stakeholders' perspectives, and elaborate on the opportunities and challenges lying ahead. Marisa Papaluca (EMA) offered an overview of the collaborative activities between the Agency and academia that currently take place in the fields of education/communication, regulatory science research, and medicines development and evaluation (see presentation). She highlighted that a stronger, more coherent collaboration between regulators and academia can greatly contribute to transitioning medicines research and development into a new trans-disciplinary model enabling full deployment of the personalised medicine paradigm. In the same perspective, Jan-Eric Litton (BBMRI-ERIC; see presentation) on behalf of the European Biological and Medical Sciences (BMS) Research Infrastructures (coordinated via the CORBEL project) provided an overview on how they can contribute to boosting the translation of biomedical discoveries to new, innovative and cost effective treatments by harmonizing user access to biological and medical technologies, high quality biological samples and data services. Hans Linden (EUFEPS; see presentation) put focus on education and training of researchers and what competencies are needed and in which area, so to build an

effective, efficient, collaborative, system for better medicines and health focused on patients, population and healthcare providers' needs. Monica Ensini (EMA) presented a preliminary analysis of the survey that, at the beginning of the year, was run with the contribution of a large set of respondents as academic organisations and individuals (a report will be published on the EMA website). The major aim of the survey was to take a snapshot of the current level of interaction between academia and regulators and to capture suggestions to respond to the opportunities and challenges that this initiative of strengthening collaboration between regulators and academia will bring.

The above mentioned presentations provided the ground for an open floor discussion. The discussion session was rich in interventions and several aspects and issues have been touched upon.
The major emerging elements are summarised below:

- opportunity to provide for a platform allowing collaborative academia and stakeholder interactions including patients, healthcare professionals, and industry;
- leveraging on the capacity of EU-wide networks to foster excellence and generate observations and consensus on key scientific issues providing high quality outcomes that will underpin evidence based regulatory science; EU-wide clinical networks were specifically highlighted;
- shared interest in strong collaboration in education, training, and communication;
- opportunity to foster harmonisation in practices and standards, where also funders could play a pivotal role;
- strategically take stock of the existing tools and initiatives.

4. The main pillars of the framework

The afternoon session provided a more detailed overview of the concrete tools and actions on which the Agency can leverage on to successfully reach the goal of enhancing collaboration with academia. The session was open by Rosa Giuliani (ESMO-HCPWP; see presentation) who presented the reflections and proposals of the HCPWP-Academia Topic Group (that she chairs with Sergio Bonini, EMA) on how to contribute to the enhancement of the collaboration between regulators and academia. The Group advocated for a more active involvement of academic healthcare professionals in regulatory activities via the enhancement of educational programmes, reciprocal participation in scientific events, and collaboration in regulatory science research projects. Zaide Frias (EMA) presented the EU Network Training Centre, a joint Heads of Medicines Agency and EMA initiative with the mission to ensure the exchange of good scientific and regulatory practices across the EU regulatory network, by harmonising training standards and offering high quality and relevant training opportunities (see presentation). She highlighted possibilities for future collaboration in providing access to academia to some of the training events organised (i.e. webinars), involvement of academia to the curricula development in some scientific areas and for the delivery of training programmes. Corinne de Vries (EMA) reviewed the activities and actions that the Agency is currently deploying to support innovation and take part in regulatory science research, highlighting the EMA Innovation Task Force, the EU Innovation Network, and the opportunities available for spending time at the Agency (e.g. National expert on secondment, visiting expert, traineeships; see presentation). Finally, Isabelle Moulon (EMA) presented the outline of

the emerging framework of collaboration in its rationale, scope, objectives and working methodology. She put forward that the pillars on which the framework will stand and grow will be to develop education and training programmes, support and collaborate in regulatory science research, and strengthen communication with a strategic plan. The open discussion that followed revolved around these three main areas. The major emerging elements are summarised below:

- 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 to allow timely and effective execution potentially underpinned by dedicated funding streams;
- consensus on the crucial importance of putting in place a communication strategy (in its tools and content) that will allow structured bidirectional exchanges.

5. Conclusions and way forward

The workshop was conceived as an opportunity of brainstorming and input gathering from academic stakeholders, and in this respect it fulfilled its promise. The exchange of information among organisers and participants and the lively, rich discussion that ensued were a confirmation that willingness and commitment are shared to successfully deliver a framework of collaboration that will allow the transition into an initial set of actions in the near future to identify roles, mandates, capabilities and capacity.

The framework is set to be finalised and adopted by EMA Management Board by the end of 2016, with its initial implementation phase starting at the beginning of 2017.

6. List of participants

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