01 February 2016
EMA/791692/2015

EMA consultation on the proposal of a collaboration framework with Academia

1. Introduction

This paper provides a brief overview of the reasons underpinning the need for establishing a framework of collaboration between the European Medicine Agency (EMA) and Academia. This initial consultation process is in the form of an online questionnaire that aims to gather information on the current status of interaction between the European medicines regulatory system[1] and Academia, to collect its expectations and needs and to open a dialogue with academic interested parties to better structure and develop the framework.

2. Background

Horizon 2020, the biggest EU Research and Innovation programme, emphasises the need to accelerate the translation of biomedical and clinical research results to medical use, with specific areas where dialogue with regulators is either required or highly recommended (e.g. rare diseases, methodologies to reduce animal testing, in-silico trials).

One of the key priorities of the recently published EU Medicines Agency Network Strategy to 2020[2] is the need to address unmet medical needs by keeping abreast of advances in science and providing an appropriate regulatory environment for those who drive innovation, including Academia. The Network Strategy also highlights the strong track record of EU regulators in supporting innovation through the National Innovation Offices and the EMA Innovation Task Force[3], providing advice and appropriate guidance. Furthermore, in the context of the current pharmaceutical legislation, initiatives such as the research networks Enpr-EMA[4] in paediatrics and ENCePP[5] in pharmacoepidemiology have been put in place and are coordinated by EMA.

[1] The European regulatory system for medicines is based on a Network (EU Medicines Agencies Network) of all national medicines competent authorities (NCAs) from Member States in the European Union and European Economic Area, and the European Medicines Agency (EMA), working closely together to ensure that medicines for human and veterinary use are safe, effective and of good quality.
[2] EU Medicines Agencies Network Strategy to 2020
[3] EMA Innovation Task Force (ITF)
[4] European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA
[5] European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)

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3. The need for an enhanced collaboration with Academia

There is already a longstanding collaboration between regulators and Academia, as clearly recognised in the Network Strategy to 2020. Indeed, Academia is the source that provides the European medicines regulatory system with thousands of experts that bring their expertise and knowledge to ensure that medicines are evaluated and monitored to the highest scientific standards (regulatory science[6]). Nevertheless, tremendous advances in science are leading to new medicines that are being developed, manufactured, assessed 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. Information is needed on the benefit-risk balance of medicines throughout their lifecycle, particularly where earlier access has been granted and when the need to proactively gather and analyse real world data is even more important.

In order to face these challenges and to address the need for patient-focused innovation, also recommended by the European Council[7], the Network Strategy to 2020 identifies key priorities which will need to be implemented in the next five years. Since Academia is an important source of innovative medicines in the European Union (as recently shown[8], see Fig 1), one key priority is that opportunities for greater collaboration and integration with Academia need to be pursued in order to translate innovation into medicinal products, to approve them through adequate and up-to-date methodologies and to monitor their use during their entire life-cycle. Notably, a recent analysis has also shown that a better dialogue with regulators has become a key positive factor in facilitating the development of safe and effective medicine to meet patients' needs[9,10].

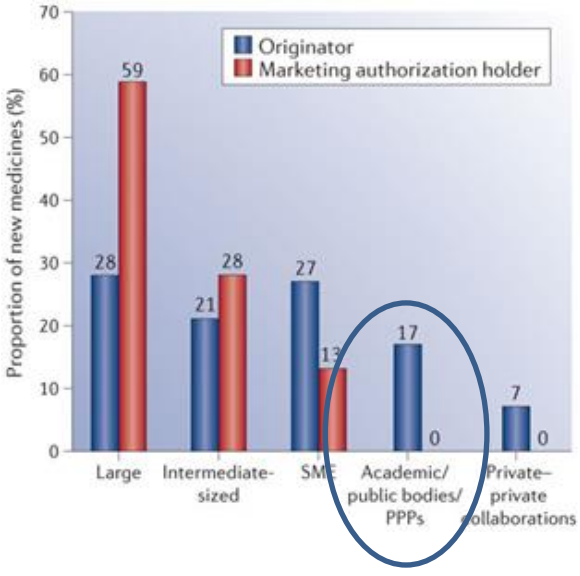

Figure 1. Originator and the marketing authorisation holder for all 94 approved products evaluated (2010-2012), divided according to organisation type. When the products were tracked back through development to their origin, academic/ Public bodies/PPPs accounted for 17%. Adapted from Nature Reviews Drug Discovery[8].

[6] For the purpose of this document 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.

[7] Council conclusions on innovation for the benefit of the patients, Council conclusion, Brussels, 1 December 2014

[8] 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.

[9] Hofer MP., Jakobsson C., Zafiropoulos N., Vamvakas S., Vetter T.,Regnstrom J., Hemmings RJ. Regulatory watch: Impact of scientific advice from the European Medicines Agency. Nature Reviews Drug Discovery. 2015; 14: 302–303.

[10] Maciulaitis R., D'Apote L., Buchanan A., Pioppo L., Schneider C. K. Clinical development of advanced therapy medicinal products in Europe: evidence that regulators must be proactive. Molecular Therapy. 2012; 20(3): 479-482.

4. Academia and Regulators, a partnership that must evolve: be part of it

In view of the growing complexity with which new medicines are being developed, evaluated and monitored it has become indispensable that Academia and regulators develop a partnership that will foster a proactive process to support innovation and channel it into the continuous evolution of regulatory science.

EMA in order to implement the strategic priority of establishing a greater collaboration with Academia (as defined in its Work programme 2016–2017), is initiating a consultation process with the following objectives:

1. Explore opportunities for a greater collaboration in order to better support Academia in generating new medicines that meet regulatory standards;
2. Channel Academia's advanced knowledge into the regulatory environment;
3. Assess the degree of awareness among Academics of the existing activities and incentives provided by regulators to support medicine development;
4. Refine regulators' understanding of Academia's needs and expectations and develop a methodology for collaboration.

You are invited to be part in this process by answering a brief on-line questionnaire that also leaves ample space for comments and suggestions.

The deadline for completing the on-line questionnaire and, if wished, sending your separate, written contribution (Academia-consultation@ema.europa.eu) is 15 April 2016. The data and contributions collected will be analysed and the results will be communicated to the respondents who will have identified themselves during this initial consultation.