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Stakeholders and Communication Division

Framework of collaboration between the European Medicines Agency and academia

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1. Executive summary

The framework aims to reinforce and further develop the collaboration between the European Medicines Agency and academia by clarifying scope, formalising and structuring interactions in the wider context of the European medicines regulatory network. It describes the objectives and the working methodology that will be undertaken to this end, in line with the principles of transparency, independence and integrity, accountability, and broad representation.

Academia is a recognised source of scientific knowledge and excellence that provides the European medicines regulatory network with expert input to ensure that medicines are evaluated and monitored to the highest scientific standards. As regulatory approaches continue to evolve the collaboration between the regulatory network and academia is necessary to ensure preparedness for future challenges and opportunities offered by advances in science and technology.

Although academic contribution has been intrinsic to the European Medicines Agency's work since its creation, gaps remain and new challenges keep emerging therefore calling for a fresh approach and the establishment of a structured framework of collaboration.

This framework will cover areas of common interest in relation to medicines for human and veterinary use. Queries relating to a specific product and/or regulatory procedure fall outside the scope of this framework document.

Formal frameworks for interacting with patients, healthcare professionals, and the pharmaceutical industry were adopted by the European Medicines Agency's Management Board in 2005, 2011 and 2015 respectively. This framework follows the recommendation made by the European Commission's Internal Audit Service in May 2014. It will complement the existing European Medicines Agency frameworks that collectively offer a platform of exchange and multi-stakeholder dialogue at the European level.

The framework overall objectives are:

1. To raise awareness of the mandate and work of the European medicines regulatory network as a means to increase academia's engagement and trust in the regulatory system that addresses society's needs;
2. To promote and further develop the regulatory support to foster the translation of academic research into novel methodologies and medicinal products which meet the regulatory standards required to address patients' and public and animal health's needs;
3. 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;
4. To work in collaboration with the regulatory network in developing regulatory science addressing e.g. novel approaches, novel endpoints, methodologies, adapting to scientific progress whilst affording appropriate patient safety.

In order to achieve its overall objectives the framework will rely on the following elements: mapping of academic entities with an interest in the regulatory activities; evolution of available expertise to keep pace with advances in scientific knowledge; identifying opportunities to promote research and knowledge generation; promoting and reinforcing dialogue through effective communication; monitoring progress and output of the cooperation with academia.

This framework of collaboration takes into consideration both organisations and their representatives pursuing education and research in all fields relevant for regulatory activities, and operating primarily at European level. In particular, it addresses organisations such as public or private education establishments awarding academic degrees, public or private non-profit organisations entities whose primary mission is to pursue research, European research infrastructures, European research consortia, and European learned societies. National Competent Authorities will continue to play a central role in managing interaction with academia at national level.

The successful implementation of the framework will necessitate close collaboration between the European Medicines Agency, the National Competent Authorities, the European Commission, and all relevant stakeholders.

The activities carried out during the framework's implementation will be reported annually to the European Medicines Agency's Management Board and published on the European Medicines Agency's website.

2. Introduction

This framework aims to reinforce and further develop the collaboration between the European Medicines Agency (EMA hereafter) and academia by clarifying scope, formalising and structuring interactions in the wider context of the European regulatory system for medicines. The European regulatory system for medicines is a unique model in the global regulatory environment. The system is based on a network of all national medicines regulatory authorities for both human and veterinary medicines from Member States in the European Union (EU) and European Economic Area, united in the Heads of Medicines Agencies (HMA)[1], and EMA, working closely together in an integrated fashion.

The mission of EMA is to foster scientific excellence in the evaluation and supervision of medicines, to protect public and animal health in the EU. In order to fulfil its science-based regulatory tasks, EMA works closely with the National Competent Authorities[2] (NCAs hereafter) that provide the expertise to its scientific committees, working parties and experts groups[3] for assessing centralised products, including centralised scientific advice, activities related to orphan and paediatric medicines, and EU wide safety procedures. In addition, EMA relies on the input from and cooperation with its stakeholders including healthcare professionals' organisations, patients and consumers' organisations, the pharmaceutical industry, veterinarians and animal breeders' organisations, and academia.

EMA has been interacting with its stakeholders including academia since its inception. Stakeholder relations have evolved over time and will vary depending on the type of stakeholder and area of activity. Formal EMA frameworks for interacting with patients[4], healthcare professionals[5], and the pharmaceutical industry[6] were adopted by the EMA's Management Board in 2005, 2011 and 2015 respectively. A framework between EMA and academia complements the existing frameworks. It follows the recommendations made by the European Commission's Internal Audit Service in May 2014.

EMA's management of stakeholder interactions is based on the principles of transparency, independence and integrity, accountability, appropriateness, broad representation, effective communication, and continuous improvement[7].

Although this framework of collaboration with academia and the framework of interaction with healthcare professionals share common objectives, the first will focus primarily on research and education, whilst the latter will continue to focus on clinical practice. Without pre-empting areas of common activity, it is recognised that advances in clinical trial methodology, personalised medicines, novel endpoints, more extensive use of real world evidence generated in the clinical care setting, and the public availability of clinical data will provide additional opportunities for engaging with healthcare professionals and academia at the interface of clinical research and clinical practice.

Collectively, these four frameworks offer a platform for exchange and multi-stakeholder dialogue at European level.

[1] The Heads of Medicines Agencies-HMA is a network of the Heads of the National Competent Authorities whose organisations are responsible for the regulation of medicinal products for human and veterinary use in the European Economic Area.
[2] The National Competent Authorities are the medicines regulatory authorities in EU Member States and the European Economic Area (EEA).
[3] EMA scientific committees, working parties and other groups
[4] Revised framework for interaction between the European Medicines Agency and patients and consumers and their organisations
[5] Revised framework for interaction between the European Medicines Agency and healthcare professionals
[6] Framework for interaction between the European Medicines Agency and industry stakeholders
[7] European Medicines Agency stakeholder relations management framework

3. Rationale – why do we need a framework?

There is a longstanding collaboration between regulators and academia, as clearly recognised in the EU Medicines Agencies Network Strategy to 2020[8]. Academia is a recognised source of scientific knowledge and excellence that provides the European medicines regulatory network with expert input[9] to ensure that medicines are evaluated and monitored to the highest scientific standards. The Network Strategy to 2020 also states that opportunities for greater collaboration with academia need to be explored to support the translation of innovation, of which academia is a major driver, into effective and safe medicinal products.

A recent publication confirms that academic research is at the origin of many of the new medicines[10] being approved in the EU[11]. Furthermore, the European Council recommendations[12] and the current EU Research and Innovation Programme Horizon 2020[13] emphasise the need to accelerate translation of biomedical and clinical research results into medical use, and highlight specific areas where dialogue with regulators is either required or highly recommended. These recommendations are supported by evidence that early interaction with regulators increases the likelihood of success in making new medicines available to patients[14].

EU regulators have a strong track record in supporting upstream innovation through advice and guidance provided by EMA Innovation Task Force[15] and, more recently, the EU Innovation Network (EU-IN[16]). In order to work closely with academia in addressing some specific areas highlighted by the current pharmaceuticals legislation, EMA put in place the research networks Enpr-EMA[17] in paediatrics and ENCePP[18] in pharmacoepidemiology.

The European pharmaceutical legislation, that established EMA and lays down the centralised procedure for authorisation and supervision of medicinal products, is based on the fundamental tenet that regulatory decisions are based on scientific evidence and the continuous advancement of scientific knowledge[19]. Moreover, to promote good governance, EU law provides that openness is considered a fundamental value underpinning the work of EU institutions, bodies and agencies[20]. It is therefore appropriate to set up a robust framework to support interaction and dialogue between EMA, academia and the broader EU scientific communities.

On this basis, the formalisation of a framework of collaboration with academia is now deemed necessary.

[8] EU Medicines Agencies Network Strategy to 2020
[9] The great majority of these experts are presently made available to the Agency, among others, by the NCAs of the EU and EEA.
[10] This publication is focused on medicines for human use.
[11] 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.
[12] Council conclusions on innovation for the benefit of the patients, Council conclusion, Brussels, 1 December 2014
[13] Horizon 2020 – Second Work Programme - Health, demographic change and well-being
[14] 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.
[15] EMA Innovation Task Force (ITF)
[16] EU-Innovation Network
[17] European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA)
[18] European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP)
[19] Regulation (EC) No 726/2004 of the European Parliament and of the Council laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency; Cf.: Article 62 and Recital 25: "*The field of activity of the Scientific Committees should be enlarged and their operating methods and composition modernised. Scientific advice for future applicants seeking marketing authorisation should be provided more generally and in greater depth. […] The committees should be able to delegate some of their evaluation duties to standing working parties open to experts from the scientific world appointed for this purpose, whilst retaining total responsibility for the scientific opinions issued. […].*"
[20] Article 15 of the Treaty on the Functioning of the European Union (TFEU).

In order to make sure that academia's needs and expectations are addressed in the framework, EMA took into account the result of the survey[21] carried out in 2016 as well as the conclusions of the Healthcare Professionals' Working Party workshop with academia[22] organised in June 2016.

4. Scope of interaction

This framework encompasses the collaboration between EMA and academia. It addresses organisations and their representatives pursuing education and research in all fields relevant to the work of EMA.

In particular, the following organisations could fall under the scope of this framework:

- Public or private higher education establishments awarding academic degrees, public or private non-profit[23] organisations/legal entities[24] whose primary mission is to pursue research, and international European interest organisations[25];
- European research infrastructures[26];
- European research consortia funded under public research programmes;
- European learned/scientific societies[27], federations and networks.

Under this framework, EMA intends to collaborate primarily with EU-level organisations. In their absence, national organisations and networks may be considered in close interaction with the NCAs concerned. NCAs will continue to play a central role in managing interactions with academia at national level. It should also be acknowledged that academic and research environments are nowadays global and operate at multiple levels. Therefore, consideration will also be given to interaction with organisations beyond the EU territory as and when appropriate.

This framework will cover areas of common interest in relation to medicines for human and veterinary use. Queries relating to a specific product and/or regulatory procedure fall outside the scope of this framework document.

The framework will provide a platform to promote dialogue, knowledge exchange on broad scientific issues and advances in medicines development, evaluation and monitoring, clinical research and real world evidence, communication focused on medicines, as well as public and animal health issues and social sciences.

5. Objectives

In order to contribute to the implementation of the EU Medicines Agencies Network Strategy to 2020, and to respond to challenges posed by emerging technologies, personalised medicines, and advanced therapies among others, this framework aims to achieve the following long-term objectives:

[21] European Medicines Agency (EMA) consultation on the proposal of a collaboration framework with academia
[22] Healthcare Professionals' Organisations Working Party (HCPWP) workshop with academia
[23] Non-profit organisation or non-profit legal entity should be understood as a legal entity which by its legal form is non-profit-making or which has a legal or statutory obligation not to distribute profits to its shareholders or individual members.
[24] Legal entity should be understood as any natural person, or any legal person created and recognised as such under national law, Union law or international law, which has legal personality and which may, acting in its own name, exercise rights and be subject to obligations.
[25] International European interest organisations are intended as organisation the majority of whose members are EU Member States or associated countries, and whose principal objective is to promote scientific and technological cooperation in Europe.
[26] Research infrastructures are defined as facilities, resources and services that are used by the research communities to conduct research and foster innovation in their fields. Where relevant, they may be used beyond research e.g. for education or public services. See also DG Research and Innovation-Infrastructures; European Strategy Forum for Research Infrastructures-ESFRI Road Map 2016 and ESFRI-landmarks.
[27] Learned/scientific societies are intended as non-profit organisations that exist to promote an academic discipline or profession, or a group of related disciplines or professions.

1. To raise awareness of the mandate and work of the European medicines regulatory network as a means to increase academia's engagement and trust in the regulatory system that addresses society's needs;
2. To promote and further develop the regulatory support on offer to foster the translation of academic research into novel methodologies and medicinal products which meet the regulatory standards;
3. 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;
4. To work in collaboration with the regulatory network developing regulatory science[28] addressing e.g. novel approaches, novel endpoints, methodologies, adapting to scientific progress whilst affording appropriate patient safety.

Achieving these objectives will necessitate close collaboration between EMA, NCAs, the European Commission, and all relevant stakeholders. NCAs will play a central role as primary convergence point to manage the interactions with national academic communities.

The objectives above will be achieved through the implementation of this framework of collaboration and its related action plan, which will be reviewed and updated as experience is gained.

6. Working methodology

EMA published an overarching stakeholder relations management framework[7] in June 2016, that sets out the guiding principles for management of all of its key stakeholder interactions to structure stakeholder relations and better support its strategic priorities. In addition, the framework of collaboration with academia takes into account the general principles for stakeholder consultation outlined in the European Commission's Staff Working Document on Better Regulation Guidelines[29], adopted in May 2015.

EMA has also put in place a new working methodology in terms of the level of stakeholder involvement (inform, consult, consult & involve, cooperate/participate), which is embedded in this framework for academia (see table 1) as well as all of the existing stakeholder frameworks (patients and consumers; healthcare professionals; industry stakeholders).

The nomination of national contact points by each NCAs will support a smooth flow of information within the network and facilitate the implementation of the framework.

In order to achieve the overall objectives identified under section 5, the framework will rely on the following elements:

1. Mapping of academic entities with an interest in regulatory activities.

The mapping of academic entities with an interest in regulatory activities enables targeted communication and facilitates interactions that are of mutual benefit. Organisations can register on a voluntary basis with EMA as an interested party to receive information and notice of public

[28] For the purpose of this document regulatory science is 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.
[29] EC Better Regulation Guidelines

consultations in selective areas of interest (via stakeholdersDB@ema.europa.eu). This information is updated regularly.

2. Evolution of available expertise to keep pace with advances in scientific knowledge.

In order to maintain an efficient and evolving regulatory ecosystem it is critical to ensure access to the best expertise across a broad range of scientific domains. Advances in research and development will be closely monitored, thus ensuring continuous access to the most appropriate expertise to support regulatory activities, including Scientific Advisory Groups, Expert Groups, Working Parties etc., and contribute to the development of regulatory guidelines. EMA maintains a public list containing details of all European experts who can be involved in its work (European experts' database[30]). These experts can be nominated by EU Member States, and are made available by the NCAs of the European Economic Area, or by EMA itself.

3. Identifying opportunities to promote research and knowledge generation.

Processes to promote knowledge generation and the involvement of academia in regulatory science research projects will be further developed. The focus will be on:

- Encouraging research to be undertaken in the areas of regulatory science and dialogue on emerging scientific issues;
- Promoting education and training on regulatory science in partnership with academia, including opportunities for staff exchange programmes;
- Contributing to the regulatory science strategic research agenda;
- Supporting evidence generation via e.g. registries, pharmacoepidemiology studies;
- Promoting and facilitating the use by academia of existing platforms (e.g. ENCePP, Enpr-EMA) and the available tools to support research and development (e.g. scientific advice/protocol assistance[31], the Innovation Task Force, the EU Innovation Network, the Science and Innovation Support Office, the SME Office[32], the PRIME scheme[33], and the qualification advice on novel methodologies[34]), as well as promoting national support tools, including national innovation offices, helplines, and scientific advice.

It should also be highlighted that EMA Healthcare Professionals' Working Party, EMA Patients and Consumers' Working Party and topic-specific workshops and events, provide a platform for exchange and dissemination of knowledge at European level.

4. Promoting and reinforcing dialogue through effective communication.

Effective dialogue between EMA and academia will underpin the implementation of this framework. Particular emphasis will be placed on:

- Acknowledging and making visible the academia's contribution to regulatory activities and scientific output;
- Enhancing regulators' understanding of the evolving academic environment, scientific advances, and the specific needs and expectations of this stakeholder group;

[30] European experts database
[31] Scientific advice and protocol assistance
[32] EMA Micro-, small- and medium-sized-enterprise (SME) office
[33] PRIME – PRIority MEdicines scheme
[34] Qualification of novel methodologies for medicine development

- Enhancing the academic community's understanding of EMA and the European medicines regulatory network's role and activities, including available tools to support research and development;
- Facilitating multi-stakeholder dialogue between academia, patients, healthcare professionals, industry, veterinarians and animal breeders, regulators, and the European Commission as deemed necessary.

The new structure will operate within EMA's management matrix to provide input on strategy and operations. The four levels of stakeholder involvement that have been identified are further detailed below:

Table 1: EMA's stakeholder relations management framework: levels of stakeholder involvement[7]	
Inform – to enable feedback	e.g. dedicated web pages, relevant news items, Q&As, information days, information materials including videos and presentations
Consult – via written consultation	e.g. public consultation on policies or guidance, surveys
Consult and Involve – via direct interactions	e.g. multi-stakeholder meetings[35], workshops, conferences, public hearings, input into the development of regulatory guidelines and other regulatory procedures
Cooperate/participate – via direct interactions	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[36]

7. Implementation and monitoring

Upon endorsement by EMA's Management Board, the framework will be implemented based on the action plan in Annex 1.

EMA will implement the framework in cooperation with the network in line with the EU Medicines Agencies Network Strategy to 2020. The planned activities will be incorporated in the annual EMA work programme.

In implementing this framework EMA's conflicts of interest policy will be adhered to in determining the scope for participation. Transparency and accountability are essential to effective engagement since, explaining and reporting on stakeholder relations will reinforce management of risk and reputation. Due to the variety of academic entities and models of collaboration that may emerge, EMA will apply the criteria already outlined in EMA frameworks of interaction with other stakeholders and those related to engagement in external regulatory science research projects, including due evaluation of potential for competing interests. EMA will publish the criteria guiding its decisions for specifically collaborating with a given academic entity or project.

[35] Including participation of the European Commission.
[36] Patients and Consumers' Working Party (PCWP); Health Care Professionals' Working Party (HCPWP); ENCePP; Enpr-EMA; SME Office, Scientific Committees Working Parties.

The activities carried out during the framework's implementation will be reported annually to EMA's Management Board and published on EMA's website. The framework and list of actions (see Annex 1) will be reviewed and updated according to experience acquired.