Press release

Collaboration with academia to be reinforced
EMA publishes framework and action plan for closer interaction

As a science-driven organisation, the European Medicines Agency (EMA) has developed a framework to formalise, structure and further develop interactions with the academic community in the context of the European medicines regulatory network.

The framework and an action plan for the next three years were adopted by EMA’s Management Board at its March 2017 meeting.

"Academia play an important role in helping the EU medicines regulatory network keep abreast of the opportunities and challenges brought by science, be it in the context of the development, assessment or safety monitoring of medicines,” says EMA’s Executive Director Guido Rasi. “The framework will allow us to integrate cutting-edge scientific knowledge more tightly into our activities. It will also help academic start-ups benefit from advice from the EU regulatory network to translate their discoveries into patient-focused medicines.”

The framework’s overall objectives are:

- raising awareness of the mandate and work of the European medicines regulatory network to increase academia’s trust in and engagement with the regulatory system;
- fostering the translation of academic research into novel methodologies and medicines which meet regulatory standards and address the needs of public and animal health;
- ensuring that the best scientific expertise and academic research are available on time to support effective evidence generation, regulatory advice and guidance, as well as decision-making in regulatory processes;
- working with academia to develop regulatory science that embraces scientific progress in medicines development without compromising patient safety, such as for example, the use of novel endpoints or novel methodologies.

The framework builds on EMA’s experience in interacting with stakeholder associations representing patients and consumers, healthcare professionals and the pharmaceutical industry, which is based on the fundamental principles of transparency, independence and integrity, accountability, and broad representation.
Along with the framework, EMA has developed an action plan which includes, among other activities, initiatives for mutual education and training, staff exchange programmes to promote mutual learning, a strategic research agenda for regulatory science and the creation of an EMA entry point for academia to receive information on available support within the EU Regulatory Network.

EMA also published today a new web page for academia providing links to content that is likely to be of interest, and a section describing the way EMA interacts with academia, with more detail on the collaboration framework and action plan and useful resources for academics.

**Reflections from academia representatives**

"This is an important step towards a strong alignment of the European excellence in regulatory and academic pharmaceutical sciences. In my discipline of systems pharmacology, I expect that this will act as a catalyst for new and better collaborations and cross-fertilisation in research, training and education. This should ultimately have a positive impact on the development of novel personalised medicines for patients," Professor Piet H. van der Graaf, Leiden Academic Centre for Drug Research (LACDR), University of Leiden, The Netherlands

"We are very excited about the new framework, as it marks an important step in Europe’s continuing efforts to boost innovation at the leading edge of science. EATRIS-ERIC and our fellow European Strategy Forum on Research Infrastructures (ESFRI) look forward to contributing to the actions arising from this initiative," Dr Giovanni Migliaccio, Scientific Director, European infrastructure for translational medicine - European Research Infrastructure Consortium (EATRIS-ERIC)

"Fondazione Telethon is directly engaged in regulatory activities, particularly to foster development of advanced therapies for treatment of rare genetic diseases. We strongly appreciate EMA’s efforts in creating an appropriate and dedicated framework within which academia and non-profit organisations, as developers of innovation, can play a pivotal role for product development, in close collaboration with regulatory authorities for the care and safety of the patients," Dr Lucia Faccio, Director of Business Development, Fondazione Telethon

"FEAM and its Member Academies seek to improve the health and safety of European citizens whilst promoting a creative and sustainable environment for medical research and training. As the discovery, development and regulatory oversight of novel medicines becomes increasingly complex, FEAM welcomes the publication by EMA of its new framework for collaboration with the academic community. An effective framework that facilitates communication and knowledge exchange between the regulators and expert academic groups will stimulate innovation in the development of new therapeutic approaches leading ultimately to improved patient benefit," Professor Bernard Charpentier, President, Federation of European Academies of Medical Sciences (FEAM)

"BioMed Alliance welcomes and fully supports EMA’s framework for closer collaboration with academia. This exciting framework will hopefully lead to opportunities for independent academic research and set out the research agenda with the regulatory authorities. The BioMed Alliance is looking forward to continuing the fruitful collaboration with EMA and working closely to improve and foster academic research in Europe," Professor Colm O’Morain, President, Alliance for Biomedical Research in Europe (BioMed Alliance).

"The dialogue between EMA and academia has already improved in time. However, this is the perfect moment to structure this interaction and bring it to the next level. The framework of collaboration is a timely initiative, which is expected to fulfil specific tasks. This is the platform needed to 1) promote regulatory awareness, 2) support academic research and 3) boost communication between the two parties. Now it is time to work!" Dr Rosa Giuliani, EU Policy Committee, European Society for Medical Oncology (ESMO)
Notes
1. This press release, together with all related documents, is available on the Agency's website: www.ema.europa.eu
2. More information on the work of the European Medicines Agency can be found on its website: www.ema.europa.eu

Contact our press officers
Tel. +44 (0)20 3660 8427
E-mail: press@ema.europa.eu
Follow us on Twitter @EMA_News