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Regulatory support for translating academic research into novel methodologies and medicines

EMA interaction with healthcare professionals and academia

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Presented by Ivana Silva on 3 March 2018, EPA Forum, 26th European Congress of Psychiatry, Nice
Public Engagement Department / Stakeholders and Communication Division
What do we do?

- Facilitate development and access to medicines
- Evaluate applications for marketing authorisation
- Monitor the safety of medicines across their life cycle
- Provide information on human and veterinary medicines to healthcare professionals and patients

Protect human and animal health
Supporting research & innovation of medicines: regulatory tools available

- Innovation task force
- Paediatric investigation plan (PIP)
- Scientific advice
- Qualification of novel methodologies
- Advanced therapy medicinal product classification
- Regulatory and administrative assistance for small-and medium-sized enterprises
- Orphan designation (including protocol assistance, fee reductions, market exclusivity)
- Priority medicines scheme (PRIME)
Working in a complex environment

Pre-submission

- Regulatory standards
- Research & development process
- Candidate medicine

Evaluation

Post-marketing

Regulatory standards

Research & development process

Medicine available to patients (or not)
A glimpse into the future

**Trends**

- Collaboration with HTAs and payers
- Transparency: clinical trials data publication
- Strengthening early dialogue with developers of medicines
- Ever more participation of patients in medicines regulation

**Challenges/Opportunities**

- Opportunistic innovative landscape
- New business models
- Need for a new approach to innovation
“Regulators need to take a new role at the crossroads between science and national healthcare systems: in order to promote public health in the current environment, they can no longer be just a gateway between those two worlds; they need to become a catalyst, an enabler for science to be translated into patient-centred healthcare and fit in the reality of healthcare systems.”

Guido Rasi, ICMRA Symposium
27 October 2017
Together, these building blocks ensure a consistent approach to stakeholder relation management across a variety of stakeholder and interaction types.
Ensuring optimal regulatory involvement in EU-wide research

- Supporting the generation of research questions
- Providing a regulatory reality check
- Using results
Liaising with European learned societies

- Clinical practice
- Clinical research
- Education
Promoting multi-stakeholder discussions

- Paediatric regulation
- Shortages and availability
- Electronic product information
- Pharmacovigilance legislation
Save the date!

An event for international regulators, NGOs and academia

8-9 March 2018 – live broadcast
Thank you for your attention

Further information

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