Faculty Disclosure

x	No, nothing to disclose
	Yes, please specify:

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

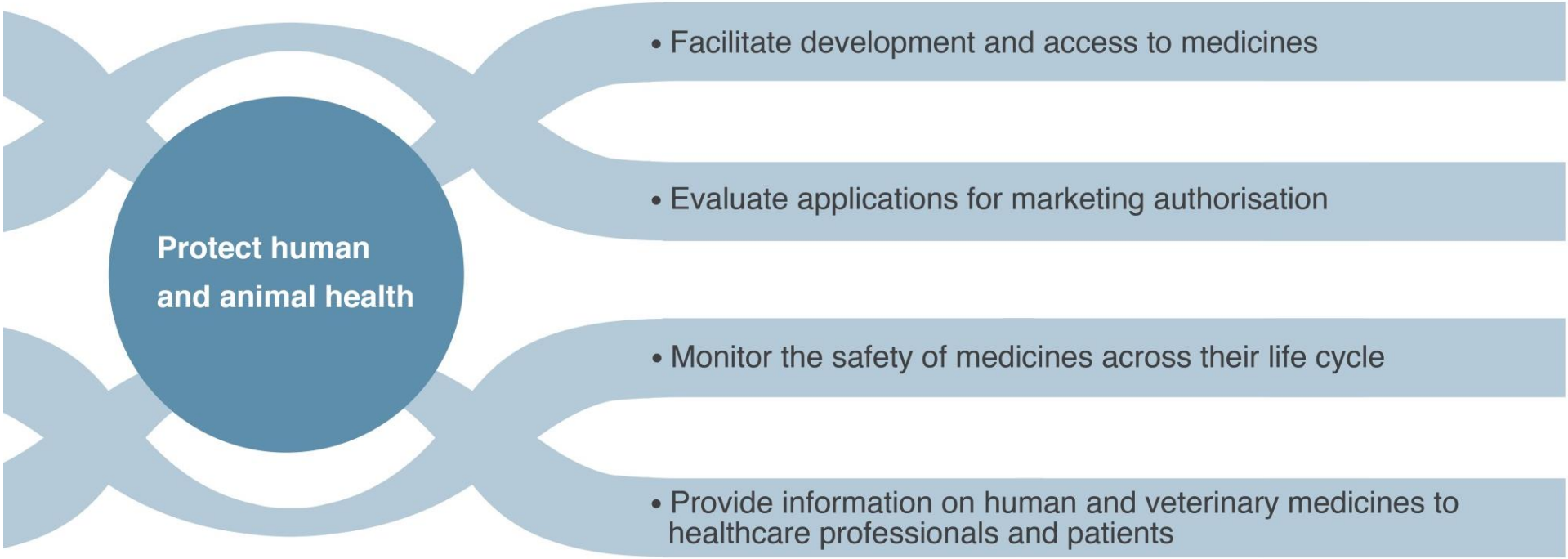
Regulatory support for translating academic research into novel methodologies and medicines

EMA interaction with healthcare professionals and academia

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?

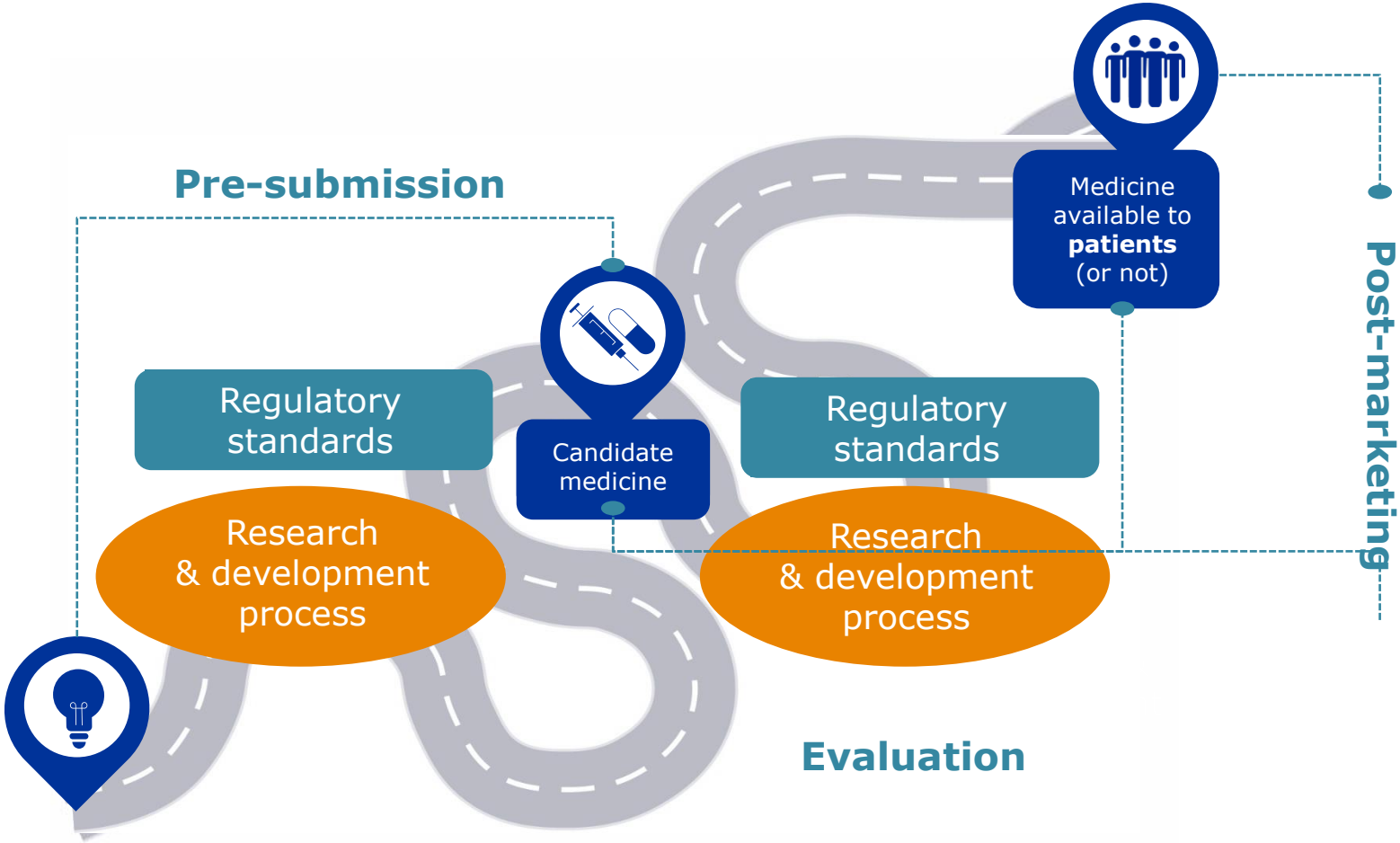

Protect human and animal health
• Facilitate development and access to medicines
• Evaluate applications for marketing authorisation
• Monitor the safety of medicines across their life cycle
• Provide information on human and veterinary medicines to healthcare professionals and patients


Every patient matters

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



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."*

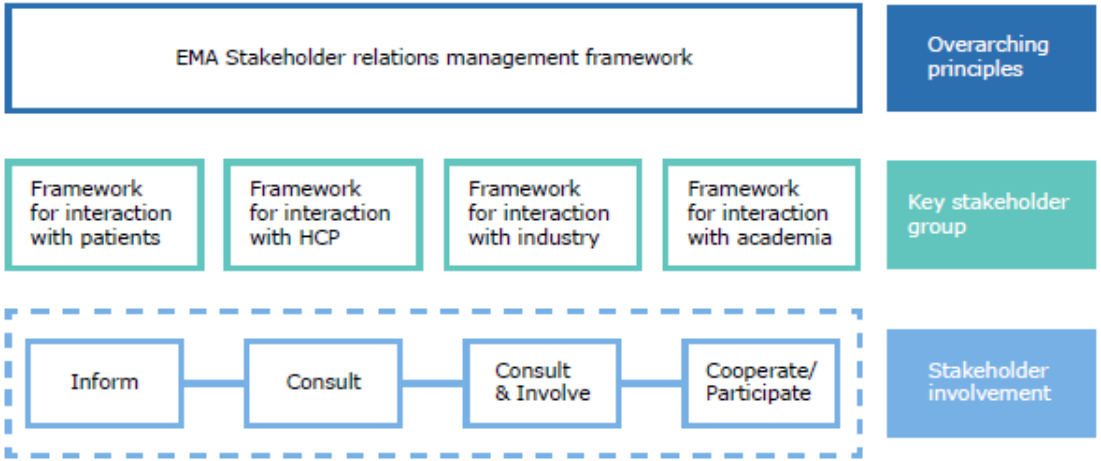
Guido Rasi, ICMRA Symposium
27 October 2017

EMA Stakeholder engagement principles

EUROPEAN MEDICINES AGENCY

Stakeholder interaction must be based on the fundamental principles:

- *Transparency*
- *Independence and integrity*
- *Accountability*
- *Appropriate interaction*
- *Broad representation*
- *Effective communication*
- *Continuous improvement*



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

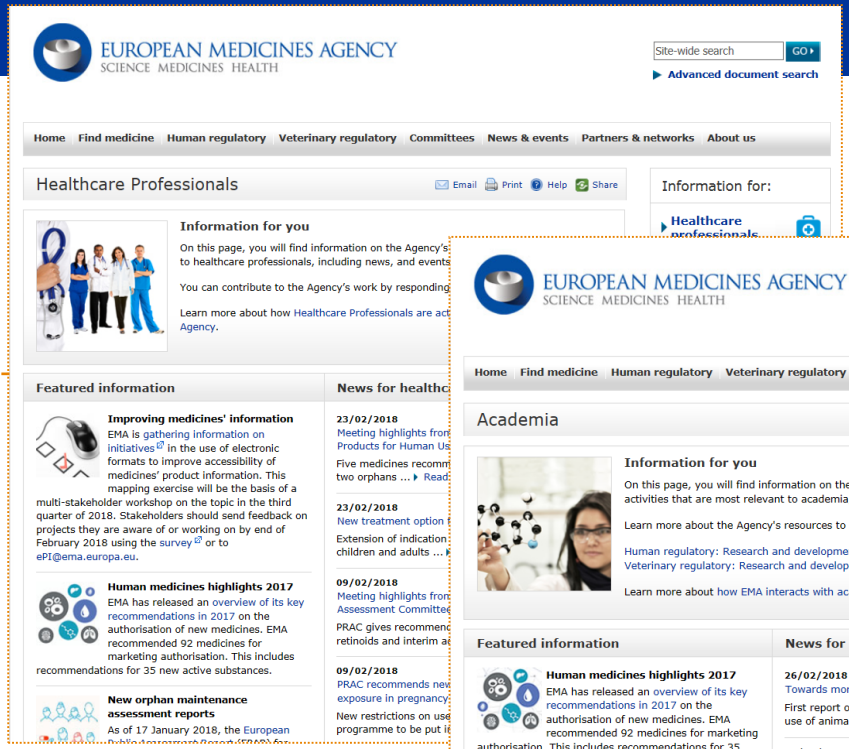
Promoting multi-stakeholder discussions

- Paediatric regulation
- Shortages and availability
- Electronic product information
- Pharmacovigilance legislation

EUROPEAN MEDICINES AGENCY

Find information for...

- Patients and carers
- Healthcare professionals
- Animal health professionals
- Pharmaceutical industry
- Media
- Academia



EUROPEAN MEDICINES AGENCY

Thank you for your attention

Further information

ivana.silva@ema.europa.eu

European Medicines Agency
30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom
Telephone +44 (0)20 3660 6000
Send a question via our website www.ema.europa.eu/contact

Follow us on **@EMA_News**