



EPA 2018
26th
EUROPEAN
CONGRESS
OF PSYCHIATRY



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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Regulatory support for translating academic research into novel methodologies and medicines

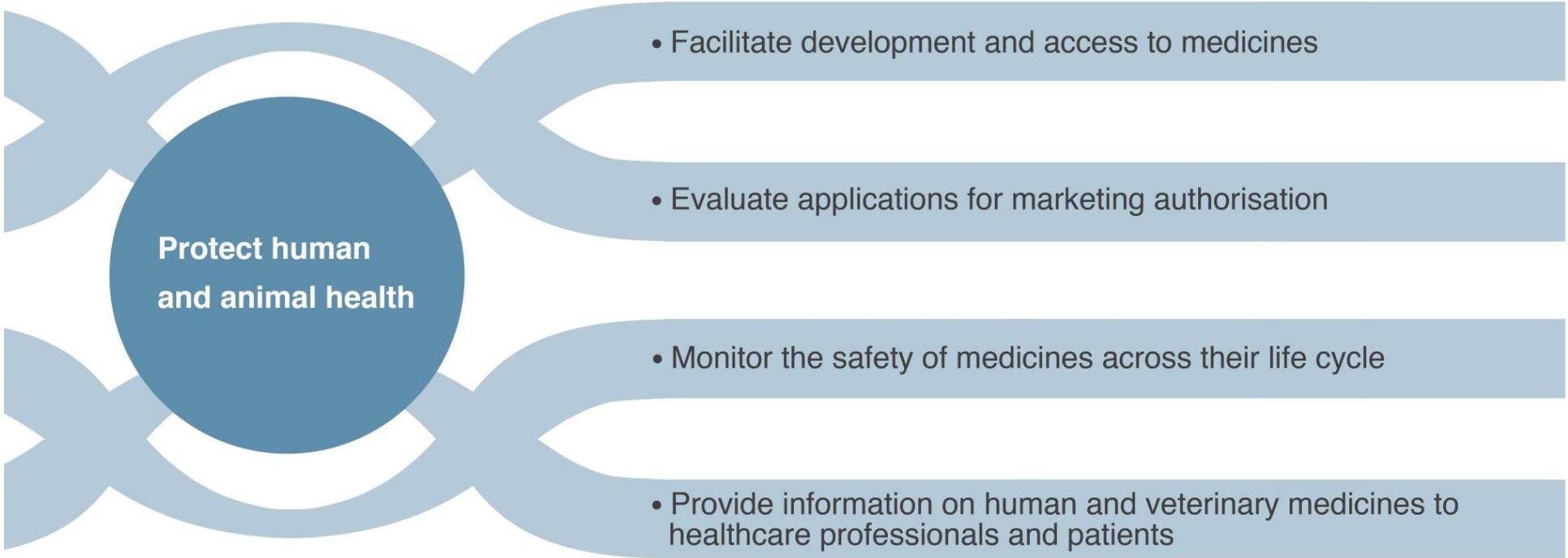
EMA interaction with healthcare professionals and academia

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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

An agency of the European Union





**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



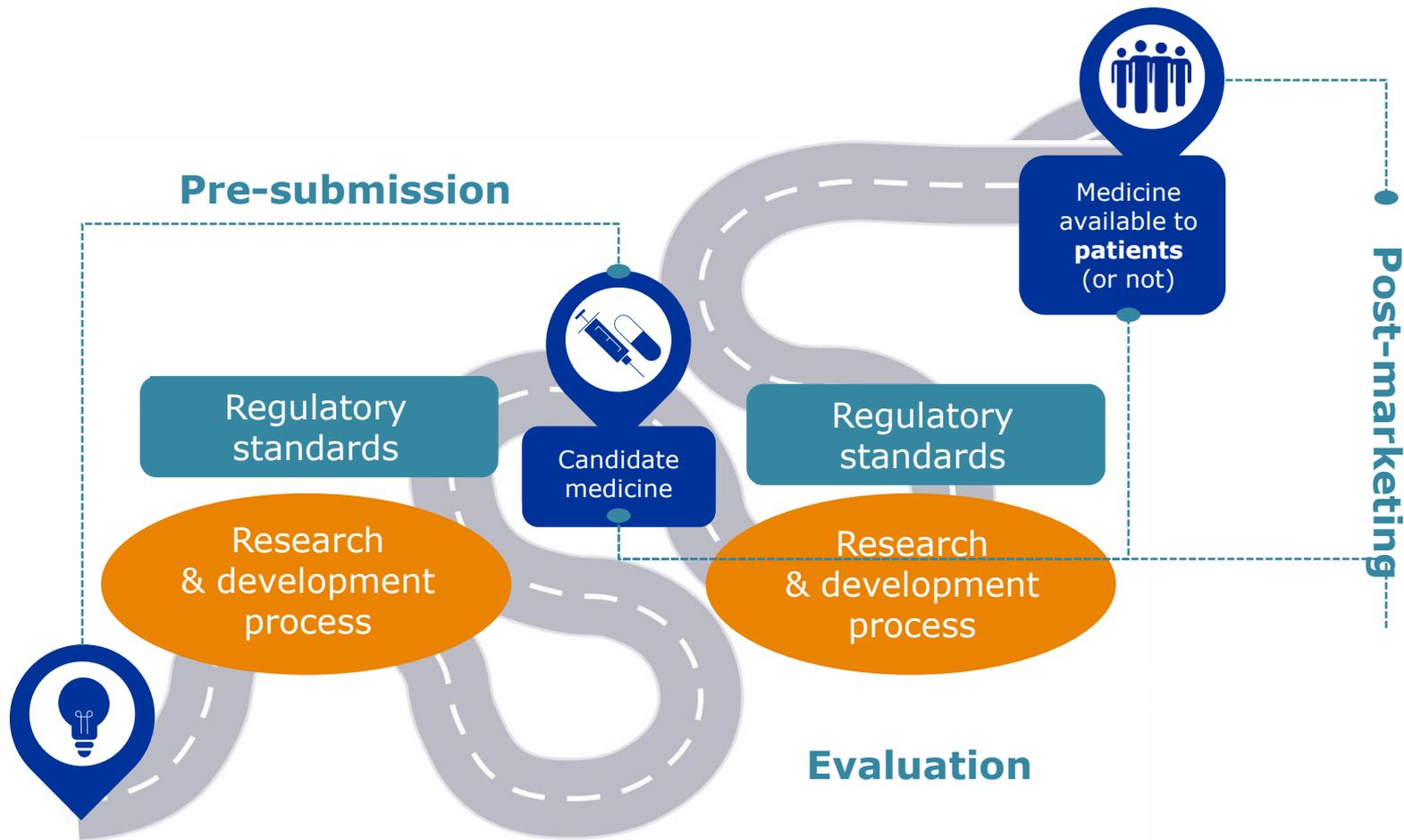
Every patient matters



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)



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



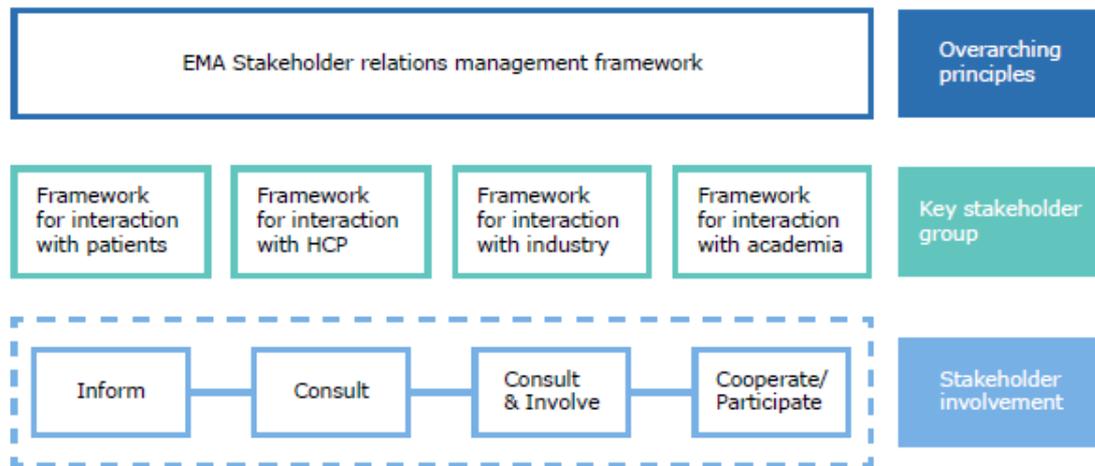
*"Regulators need to take a **new role** at the **crossroads** between **science and national healthcare systems**:*

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

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



**Working with
healthcare
professionals**





Promoting multi-stakeholder discussions



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



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Featured information

Improving medicines' information

EMA is gathering information on initiatives in the use of electronic formats to improve accessibility of medicines' product information. This mapping exercise will be the basis of a multi-stakeholder workshop on the topic in the third quarter of 2018. Stakeholders should send feedback on projects they are aware of or working on by end of February 2018 using the survey or to ePI@ema.europa.eu.

Human medicines highlights 2017

EMA has released an overview of its key recommendations in 2017 on the authorisation of new medicines. EMA recommended 92 medicines for marketing authorisation. This includes recommendations for 35 new active substances.

New orphan maintenance assessment reports

As of 17 January 2018, the European

News for healthcare

23/02/2018

Meeting highlights from Products for Human Use

Five medicines recommended for two orphans ... ▶ Read more

23/02/2018

New treatment option for Extension of indication: children and adults ... ▶ Read more

09/02/2018

Meeting highlights from Assessment Committee

PRAC gives recommendations on retinoids and interim a

09/02/2018

PRAC recommends new exposure in pregnancy. New restrictions on use programme to be put i



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Information for you

On this page, you will find information on the European Medicines Agency's (EMA) activities that are most relevant to academia, including news and events.

Learn more about the Agency's resources to support medicine development:

- Human regulatory: Research and development
- Veterinary regulatory: Research and development

Learn more about how EMA interacts with academia.

Featured information

Human medicines highlights 2017

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Horizon 2020 research funding

EMA has published a dedicated webpage with information that may be helpful for researchers applying for funding under the European Commission's Horizon 2020 programme in the area of health.

ENCePP: Key achievements of ENCePP in its first ten years

To mark the tenth anniversary of the EMA-coordinated European Network of Centres for Pharmacovigilance and Pharmacovigilance (ENCePP), the Agency has published an infosheet highlighting its key achievements. ENCePP has made a significant impact on the benefit-risk

News for academia

26/02/2018

Towards more ethical use of animals in medicine testing

First report on EMA's actions to replace, reduce, refine use of animals in medical research ... ▶ Read more

23/02/2018

Meeting highlights from the Committee for Medicinal Products for Human Use (CHMP) 19-22 February 2018

Five medicines recommended for approval, including two orphans ... ▶ Read more

23/02/2018

New treatment option for rare inflammatory disease

Extension of indication of Kineret for Still's disease in children and adults ... ▶ Read more

16/02/2018

Committee for Medicinal Products for Veterinary Use (CVMP) meeting of 13-15 February 2018

CVMP recommends changes to product information for some veterinary medicines containing enrofloxacin, to reduce development of antimicrobial resistance in

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Working for every patient in Europe



Horizon 2020 programme



Innovation in medicines

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Save the date!

An event for international regulators,
NGOs and academia



Thank you for your attention

Further information

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