



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA framework of collaboration with academia

Veterinary Innovation Day, 19 April 2018

Presented by Monica Ensini
National Expert on Secondment
Public Engagement Department
Stakeholders and Communication Division

An agency of the European Union





Closing the gap between academia and regulators: *a reality*



European Council conclusions on innovation for the benefit of patients (1-12-2014): "...in order to stimulate development, there is a need to facilitate the translation of scientific advance into innovative medicinal products that meet regulatory standards".



Horizon 2020 framework programme: Health, demographic change and well-being, work programme 2016-2017 "...Engagement with regulators and consideration of the regulatory framework issues are highly recommended."

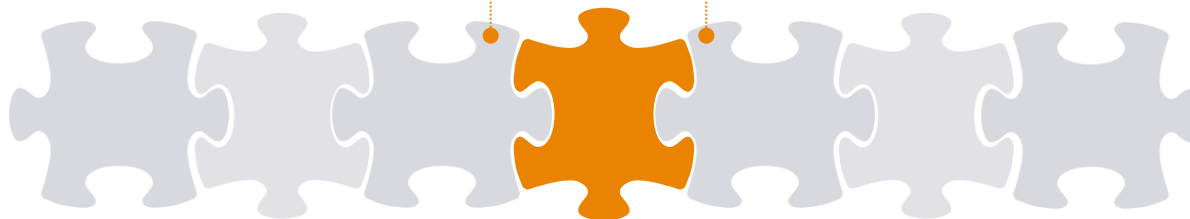


EU Medicines Agencies Network strategy to 2020 "...support for patient focused innovation and contribute to a vibrant life science sector in Europe."



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European Medicine Agency work plan 2016-2017 "...the Agency will support a strengthening of the collaboration and integration across the network and with academia..."





"EMA wants to move to a new level of collaboration with academia. Science is progressing fast and we see an unprecedented level of complexity in the development and evaluation of new medicine. Academia play an important role in helping the EU medicines regulatory network to keep abreast of the opportunities and challenges brought by science and to have access to the right expertise to evaluate these innovative medicines. Interaction with EU regulators and a better understanding of the regulatory environment can help academia translate their discoveries into patient-focused medicines. I believe that working more closely together will bring great benefits to public health".

Guido Rasi, EMA Executive Director

Framework of collaboration with academia

Purpose

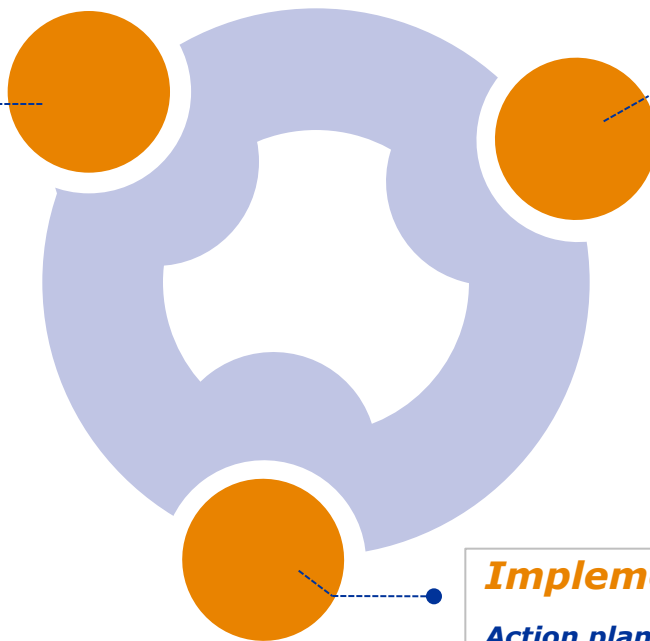
*Formalise and structure the **collaboration between the Agency and Academia** in the wider context of the European Regulatory System for Medicines*

Scope

***Areas of common interest** in relation to medicines for human and veterinary use*

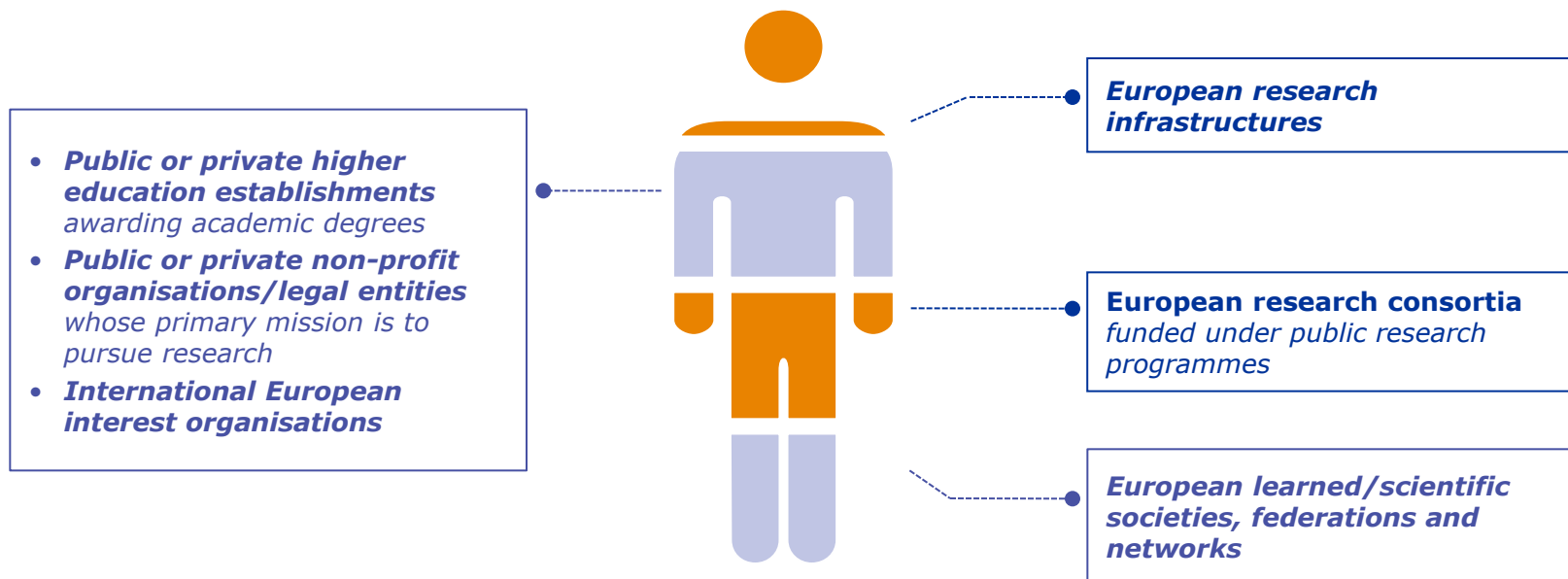
Implementation

Action plan, monitoring and reporting



Framework of collaboration with academia

Scope (stakeholders)





Framework of collaboration with academia

Objectives

1

To **raise awareness of the mandate and work of the European medicines regulatory network**

2

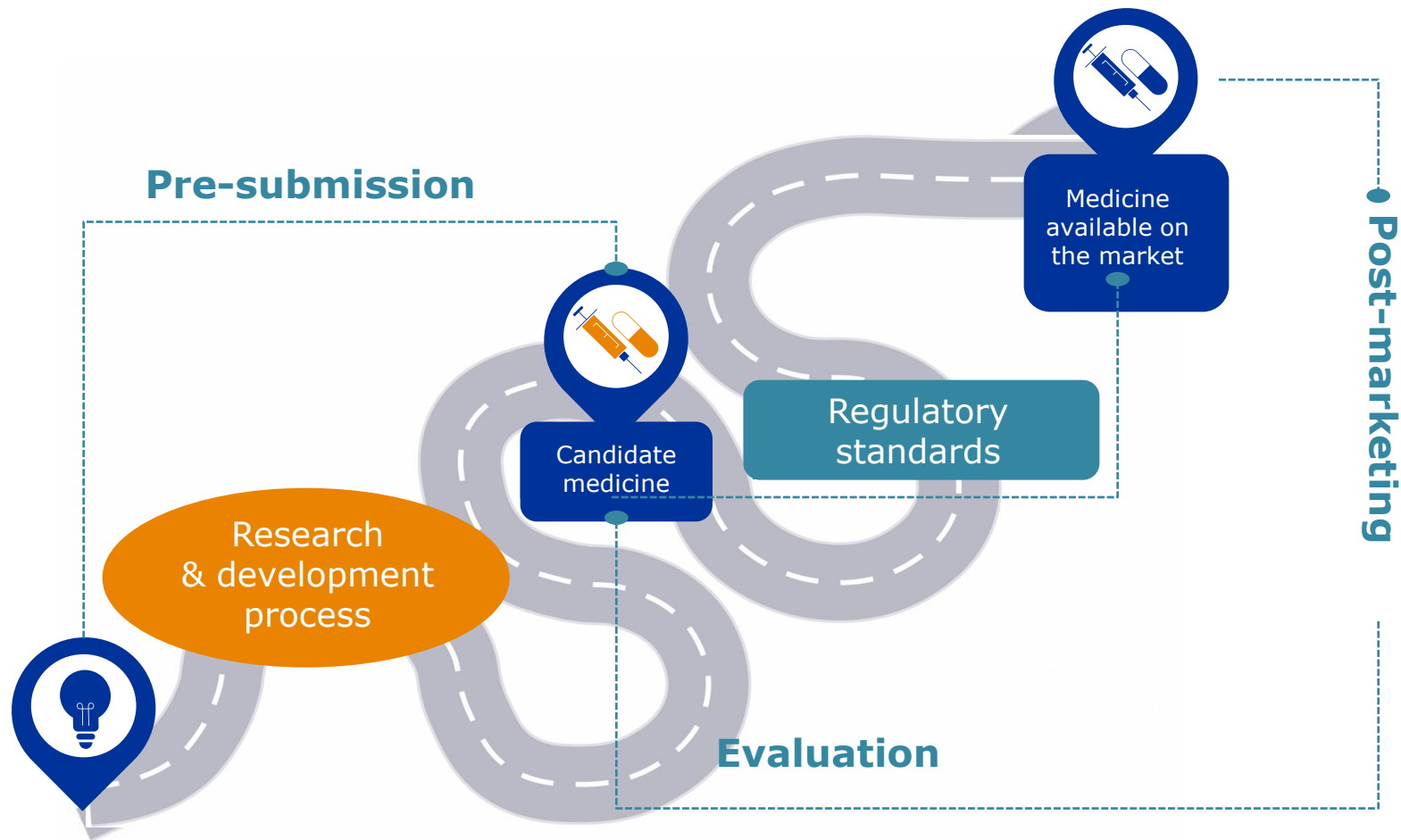
To **promote and further develop the regulatory support to foster the translation of academic research** into novel methodologies and medicinal products

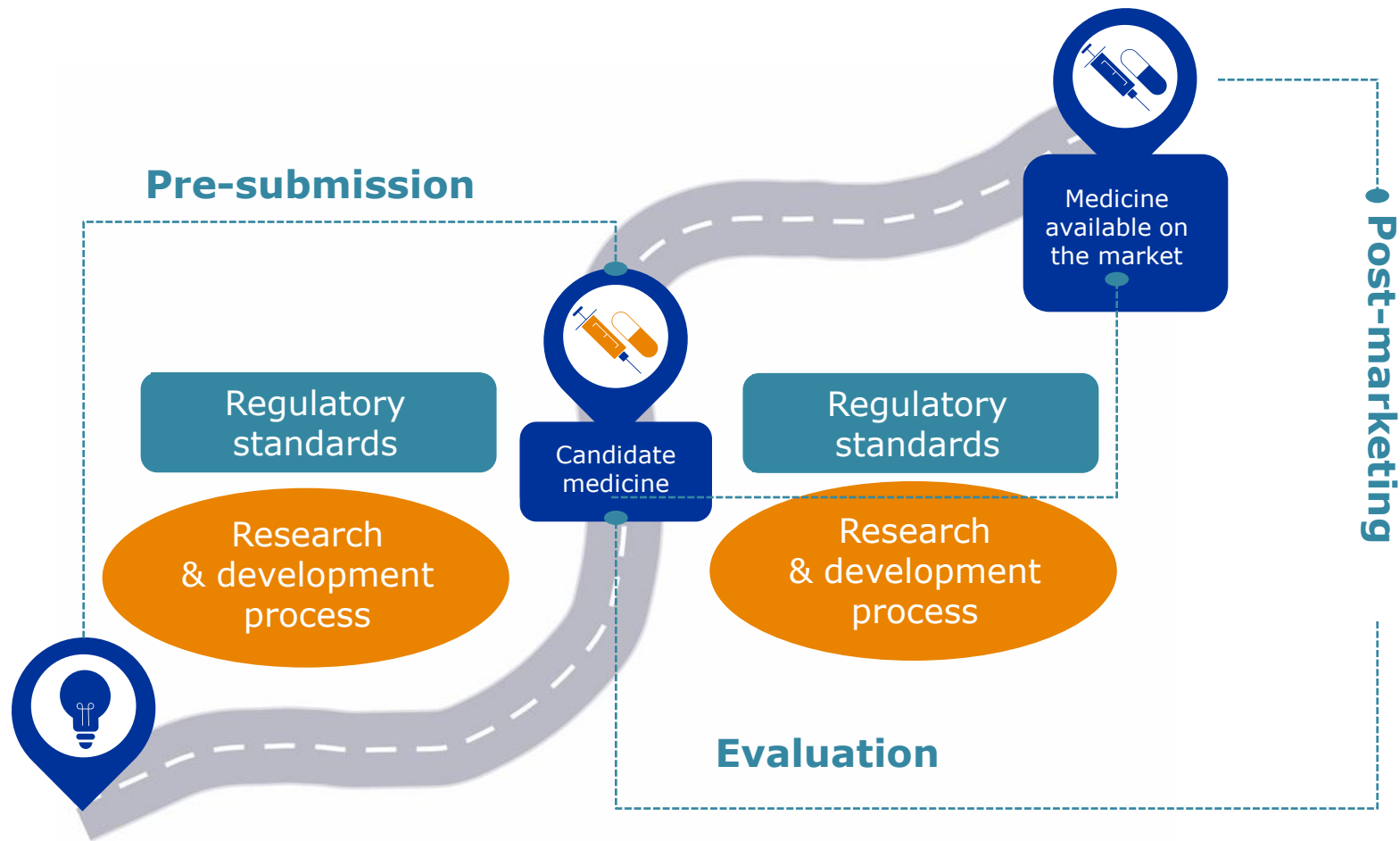
3

To ensure that the **best scientific expertise and academic research are available** to the regulatory processes

4

To **collaborate on relevant areas of research relating to regulatory science**







Framework of collaboration with academia

Methodology



INFORM

e.g. dedicated web pages, relevant news items, Q&As, information days, information materials



CONSULT

e.g. public consultation on policies or guidance, surveys



CONSULT & INVOLVE

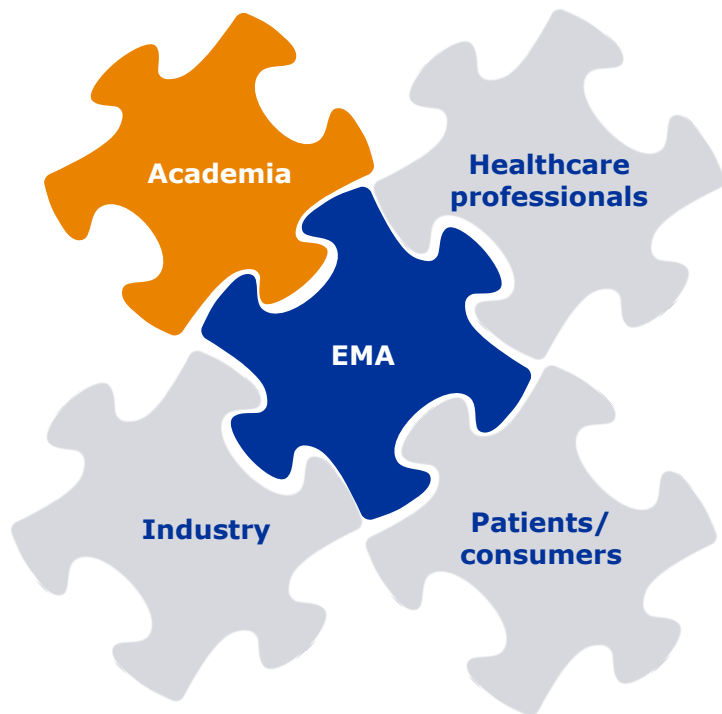
e.g. multi-stakeholder meetings, workshops, conferences, development of regulatory guidelines



COOPERATE

e.g. participation to research projects, cooperation in activities of education and training, cooperation with established EMA stakeholders and networks

Promoting multi-stakeholder discussions



- Antimicrobial resistance
- Availability of medicines
- Challenges of the new regulation ("Animal Health Law")
- Safety of medicines and risk assessment
- Preclinical and clinical research



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Animal health professionals



Information for you

On this page, you will find information on the Agency's activities, that are most relevant to Animal health professionals such as pet owners.

You can contribute to the Agency's work by responding to surveys.

Learn more about the European Medicines Agency's role for Veterinary Use (CVMP) and its role regarding

Featured information



Veterinary pharmacovigilance bulletin 2017

EMA's annual bulletin on veterinary pharmacovigilance provides information on the main outcome of post-marketing surveillance activities for veterinary medicines. The bulletin summarises recommendations to amend the safety warnings and highlights ongoing monitoring of several centrally authorised products. The latest bulletin highlights that in 2017, the electronic reporting of adverse events to EudraVigilance Veterinary (EVVet) increased by near 25%.



Veterinary medicines highlights 2017

EMA has released an overview of its key recommendations in 2017 on the authorisation of new veterinary medicines. EMA recommended 18 veterinary medicines for marketing authorisation. This includes recommendations for 7 new active substances

News for animal health professionals

27/03/2018
European Medicines Agency
EMA closed from until 7:30 on Tuesday 27 March 2018

26/03/2018
EU recommends vaccine composition
EU advice based on more data

22/03/2018
Increased report medicines helps veterinarians
Veterinarians are to facilitate detection of more

16/03/2018



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Academia

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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

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.



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.



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 to

Information for:

► Academia



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Working for every patient in Europe



Horizon 2020 programme

Innovation in medicines



Thank you

Further information

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