EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Stakeholder interaction in EMA innovation support

EMA Veterinary medicines innovation day

Presented by Dr Ivo Claassen on 19 April 2018
Head of Veterinary Medicines Division

Stakeholder interaction and frameworks supporting innovation

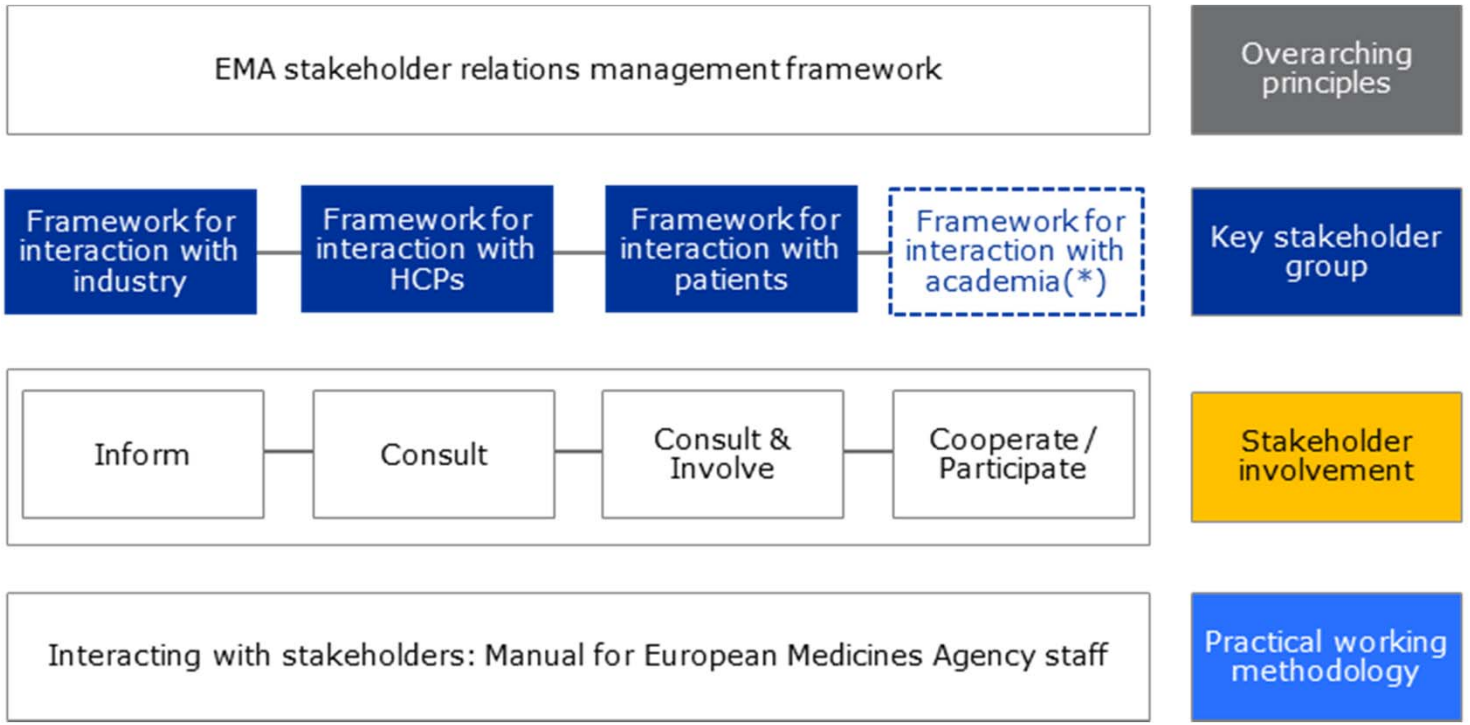
EMA has established contacts with its stakeholders

- *Definition: organisations, associations and parties interacting with the European Medicines Agency, which have an interest in or are influenced by the work of the EMA and its partners*.

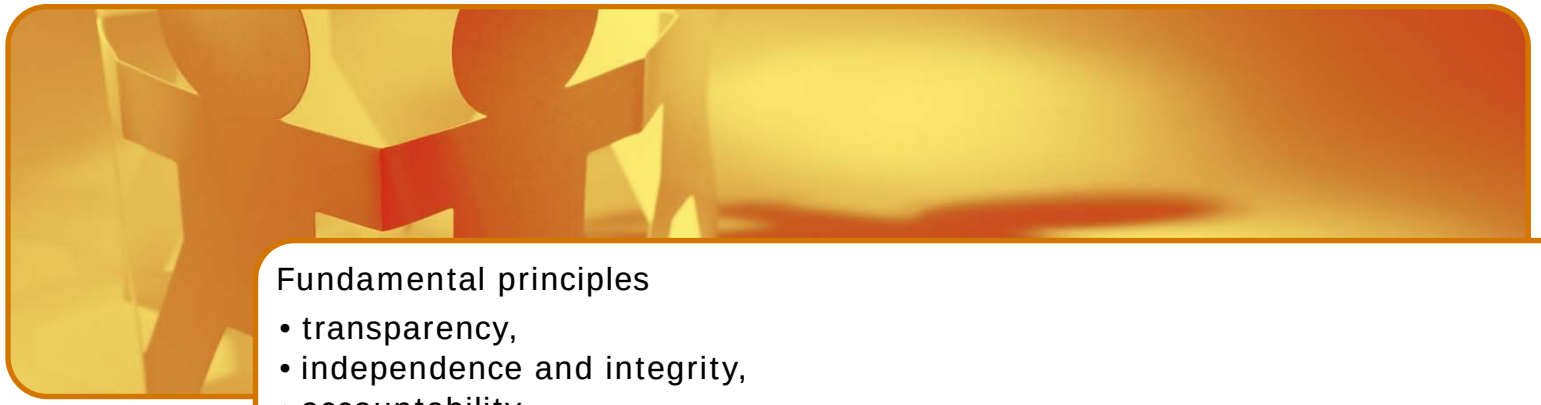
EMA has developed a series of framework documents to formalise its interaction with its main stakeholder groups

- To foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health;
- To promote appropriate engagement and dialogue on topics concerning medicines for human and veterinary use;

EMA stakeholder relations management



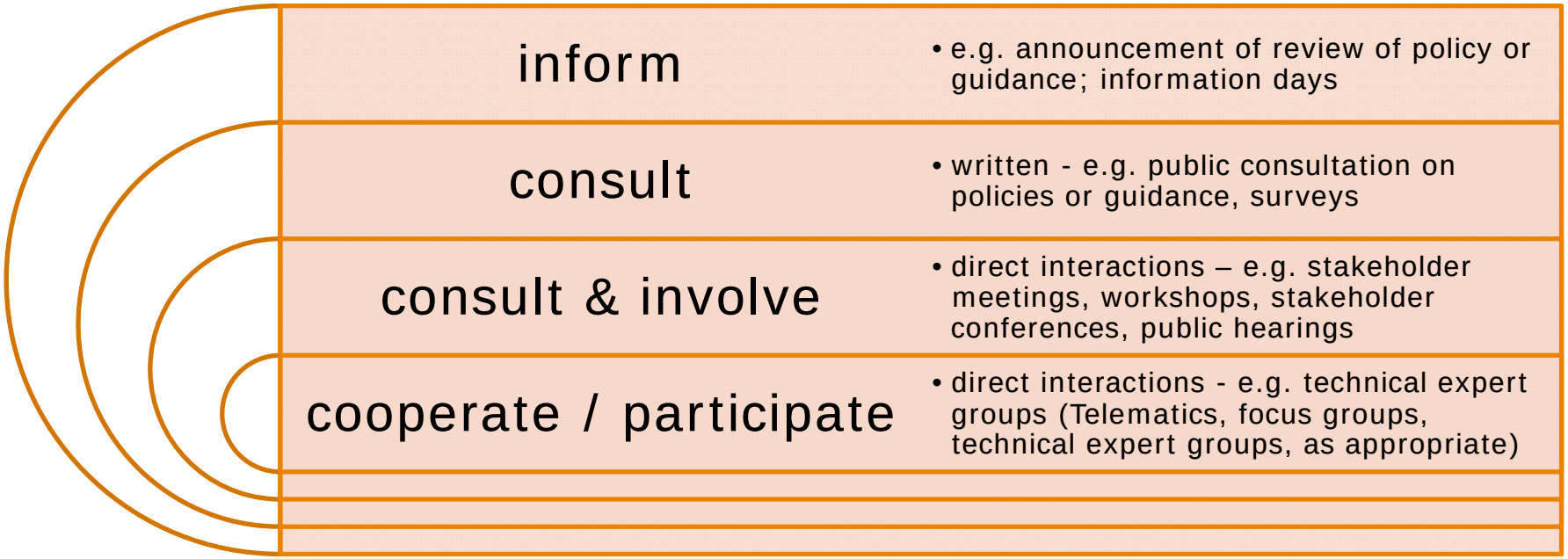
Stakeholder interaction principles



Fundamental principles

- transparency,
- independence and integrity,
- accountability,
- appropriate interaction,
- broad representation,
- effective communication, and
- continuous improvement.

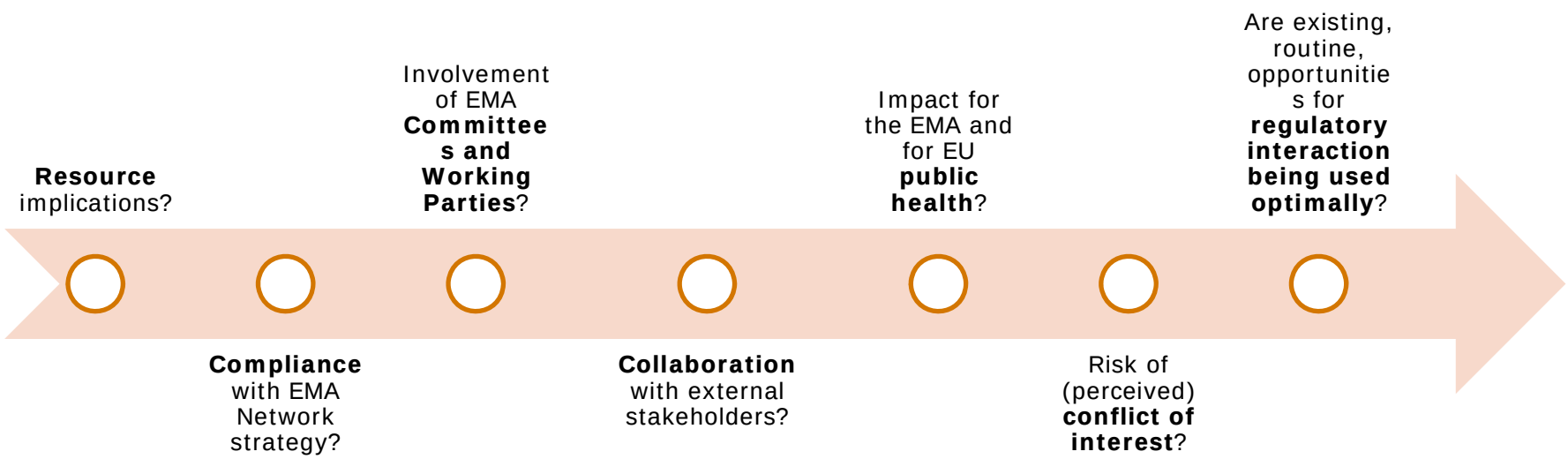
Four levels of stakeholder involvement



Interactions in veterinary medicines

Workshops and guidelines	•Organising scientific workshops, consulting on guidelines
Data analysis and publication	•Analysing in-house data and publishing results
Visiting experts	•Providing for visiting academics, e.g. seconded national experts
Conference participation	•Participating in scientific conferences
External boards	•Providing experts to external/scientific/regulatory advisory boards
Regulatory science initiatives	•Launching in-house initiatives on topics of interest in regulatory science
External projects	•Possibility to commission, coordinate or actively participate

Factors determining EMA involvement



EMA engagement in external research initiatives

- Policy on approach to engaging in external regulatory science projects and process improvement research activities for public and animal health
- Sets the criteria that should be followed when considering Agency engagement in externally funded regulatory science activities
- Highlights the existing possibilities to interact with EMA
- Provides a framework for dealing with third party requests
- Outcomes of initiatives not necessarily binding to EMA

http://www.ema.europa.eu/docs/en_GB/document_library/Other/2013/03/WC500139888.pdf


dialogue
high standards
engagement
research and development
EMA supports
collaboration
innovation
progress
knowledge sharing
awareness

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Any questions?

Further information

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Back up slides

Academia

EMA framework agreed in March 2017

Objectives:

- raise awareness of EMA's role within the European medicines regulatory network;
- promote and further develop regulatory support for translating academic research into novel methodologies and medicines;
- ensure that the best scientific expertise and academic research is available to inform regulatory decision-making;
- collaborate on areas of research on regulatory science, such as novel approaches, endpoints and methodologies.

Academia

Academics and researchers participate in the work of the Agency in several ways, including:

- as members and experts of its scientific committees and working parties;
- in the preparation of scientific guidelines;
- as seconded national experts;
- as visiting experts;
- taking part in the Agency's conferences and workshops.

HPC

EMA framework agreed in December 2016,

Objectives:

- support the Agency in accessing the best independent expertise in any matter related to medicines;
- contribute to more efficient and targeted communication to healthcare professionals;
- enhance understanding of the role of the EU medicines regulatory network.

HPC

HPC participate in the work of the Agency in several ways, including:

- as members of the Management Board;
- as members of its scientific committees;
- responding to specific requests from the Agency's scientific committees and working parties;
- taking part in discussions on the development and authorisation of medicines;
- reviewing written information on medicines prepared by the Agency;
- being involved in the preparation of guidelines;
- taking part in Agency conferences and workshops.

Industry

- One of the EMA's main stakeholders.
- Framework objectives:
  - exchange views and promote dialogue concerning medicines;
  - improve communication and provide efficient, targeted and timely information proactively;
  - enhance understanding of EU medicines regulatory framework and role of the regulators;
  - co-operate with established networks and alliances;
  - increase transparency of stakeholders engaging with the EMA.