



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA reorganisation

EMA/IFAH-Europe Info Day 2015



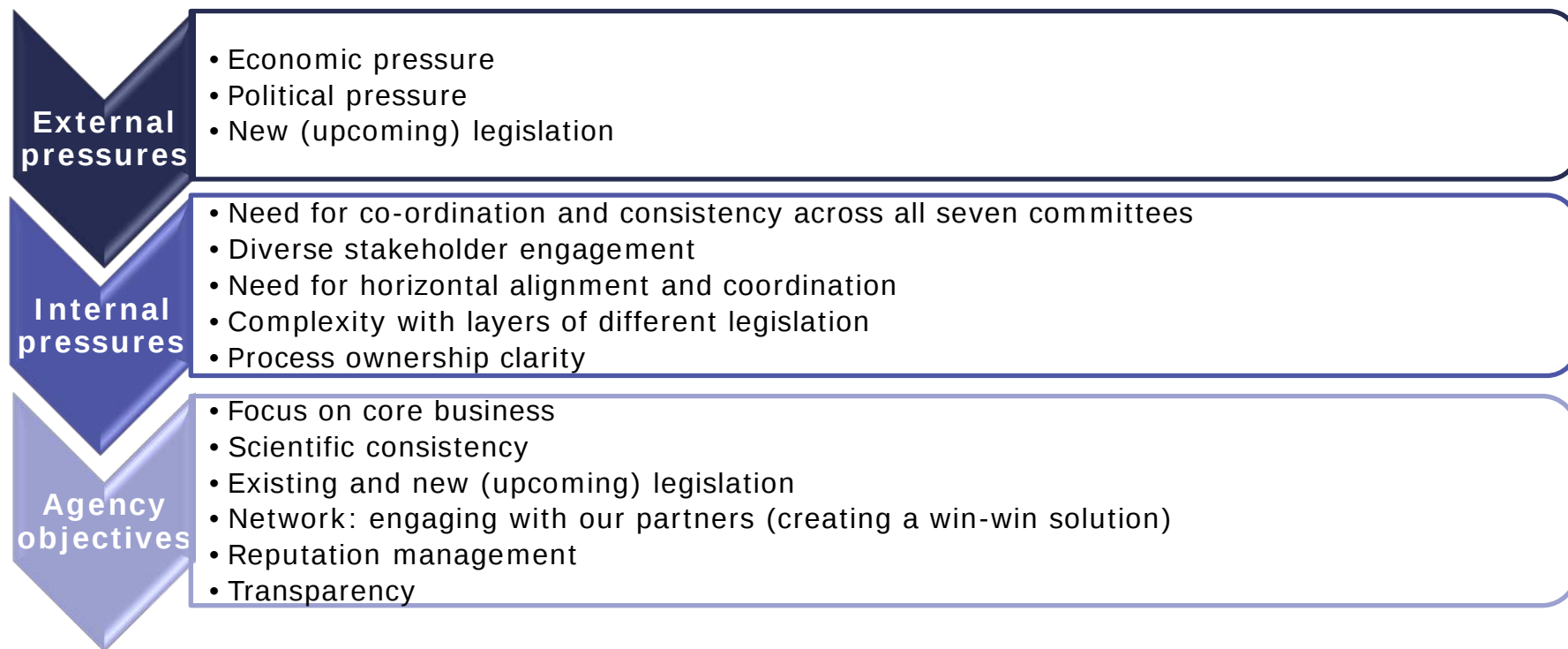
Presented by Kornelia Grein on 13 March 2015
Head of Veterinary Medicines Department

An agency of the European Union





Triggers for re-organisation:





EMA Mission statement

Foster scientific excellence in the evaluation and supervision of medicines for the benefit of public and animal health.





Aim of the reorganisation

- To reshape the EMA to enable us to use our resources more efficiently and effectively and ensure that the Agency is better prepared for future legislative and policy challenges:
- To better support the scientific work of the EMA committees
- To better share the knowledge and information held by EMA throughout the EU medicines regulatory network
- To better meet the need of our stakeholders and partners



New organisation – main changes

- Creation of a new operating model for how medicines are managed through their entire lifecycle at the Agency
- Creation of four new Operational Divisions dealing with medicines for human use

Human Medicines
Research &
Development
Support Division
D

Human Medicines
Evaluation
Division
E

Procedure
Management &
Business Support
Division
B

Inspections &
Human Medicines
Pharmacovigilance
Division
P

- New Division for Stakeholders and communication

Stakeholder and
Communication
S



Corporate Stakeholders Department



Purpose

Formalise and streamline our interaction with industry stakeholder groups.

Scope

Interaction between the Agency and industry associations.

Next steps

Finalise high-level framework for interaction, establish eligibility criteria, launch of "Industry Stakeholder" information webpage.

Key principles

- *Facilitate & streamline communication*
- *Structured interaction*
- *Accountability*
- *Transparency*
- *Broad representation of the industry*



Corporate Stakeholder Department



Purpose

Aims to formalise and structure our interaction with industry stakeholder groups.

Scope

Framework will cover interaction between Agency and industry associations.

Implementation

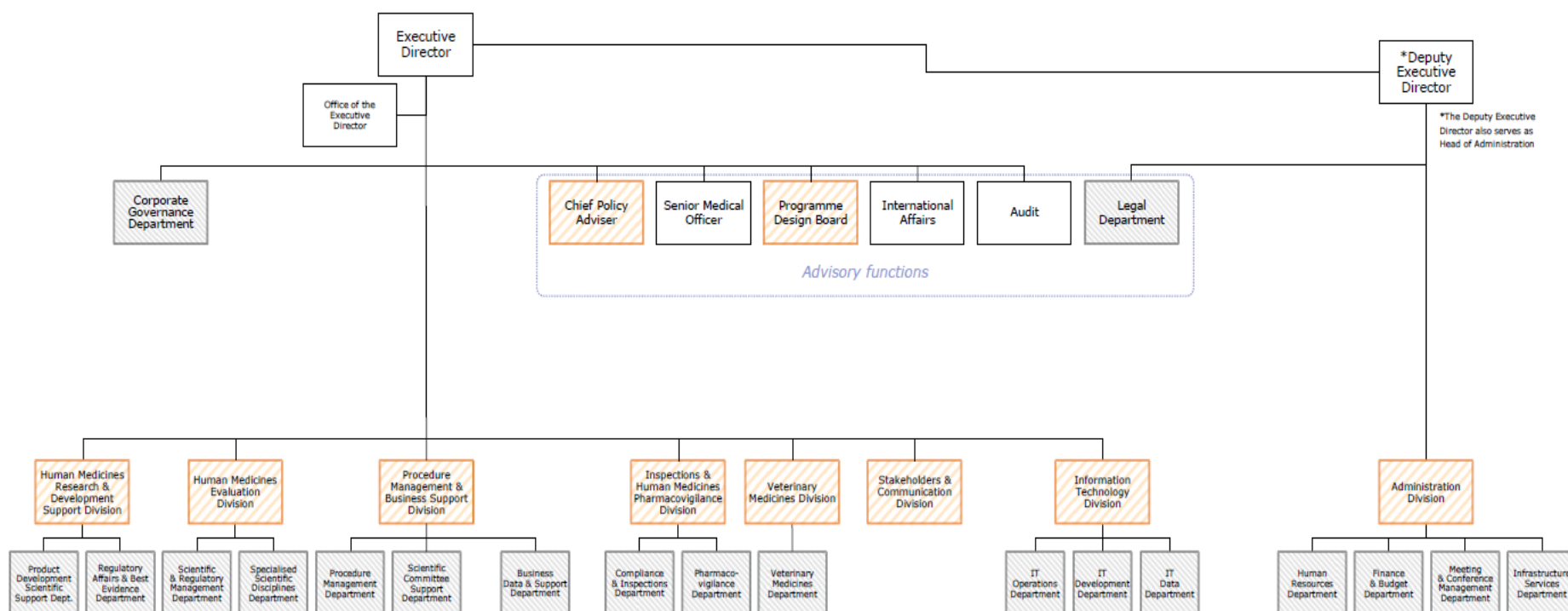
Action plan, monitoring and reporting on the interaction.

Key principles

- *Facilitate & streamline communication*
- *Structured interaction*
- *Accountability*
- *Transparency*
- *Broad representation of the industry*



New organisation structure





Veterinary division

- No change for the current entities responsible for veterinary medicines so far
- Veterinary division has been re-focused to deal solely with veterinary medicines and animal health.
- Same principles for operation apply
- Some functions centralised
- Review will continue if processes for veterinary medicines should be improved to ensure a more efficient level of service



Our values

Excellence

We foster regulatory, scientific and professional capability, competence and knowledge to provide state-of-the-art advice and independent expertise.

Commitment

We are passionate about our work and our mission to improve public and animal health in a proactive and innovative way.

Reliability

We deliver what we promise.

Respect

We treat our staff, network, partners and stakeholders fairly and with respect, by encouraging open dialogue and responding to their needs.

Accountability

Our decisions, activities and outcomes are transparent through open ways of working and mutual trust.



Thank you for your attention!