



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

European Medicines Agency re-organisation

Supporting the work of the committees

Presentation to the PCWP/HCPWP joint meeting – 25
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An agency of the European Union





New organisation structure to focus on three key elements

- Better support the scientific work of the EMA committees
- Better share the knowledge and information the Agency holds throughout the European Union (EU) medicines regulatory network
- Better meet the needs of our stakeholders and partners.



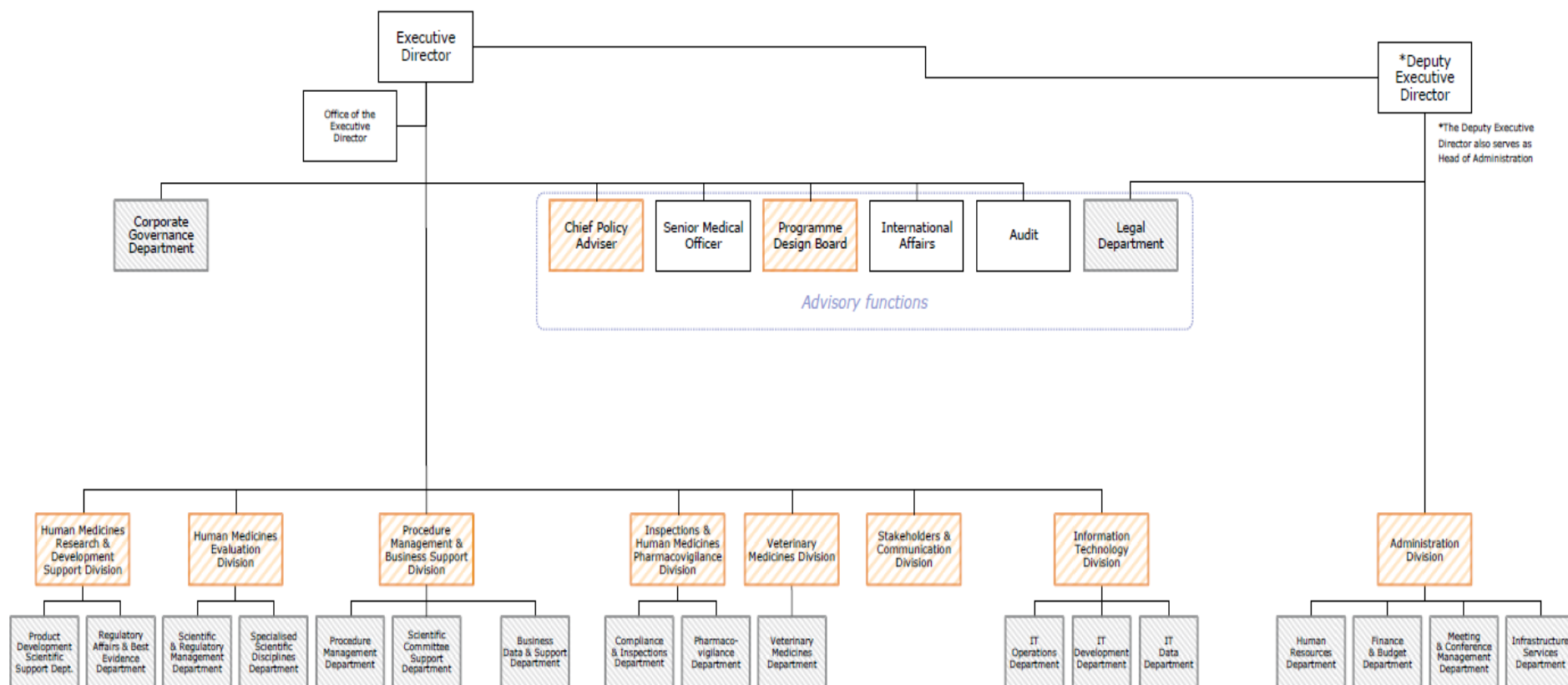
New organisation structure: reason why

Reshaping a regulatory agency fit for the future

- Economic pressures
- New challenges, e.g. future legislative and policy challenges
- To do more with less: a more effective and efficient use of existing resources



New organisation structure





New organisation structure - main changes

- Creation of four new 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

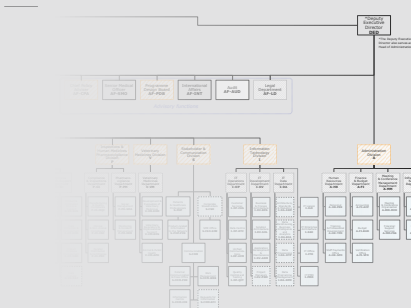
Inspections &
Human Medicines
Pharmacovigilance
Division
P

- New Division for stakeholders and communication to provide improved coordination of the Agency's relations with stakeholders
- No change for the current entities responsible for veterinary medicines, IT and administration
- Advisory functions, which provide advice the Executive Director on operational and scientific issues in their fields of expertise.

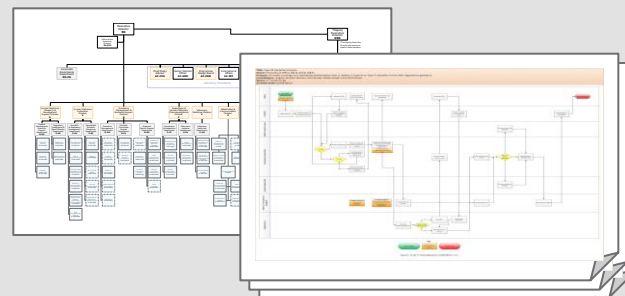
The start of a journey

- The Agency will be looking at all operations over the course of next 12-18 months to design processes and refine structure.

The transition to the new structure started on 1 August 2013



The new structure and revised operational processes will be completed in 2014



- Throughout the transition period we will ensure continuity of operations for medicine evaluation and supervision



What it means for now

- The continuity of the EMA's operations will be ensured at all times during the period of reorganisation.
- All contact points will remain unchanged for the time being.
- Any changes that will be made will be communicated to the EMA's stakeholders.