



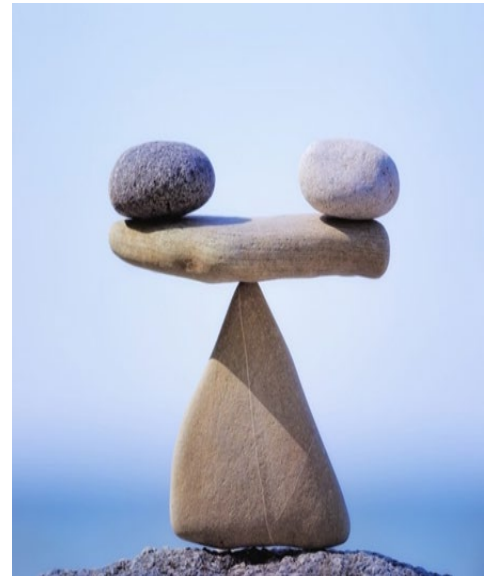
# EMA Regulatory Science to 2025

**Florian Schmidt, DG SANTE**

# New Commission - Priorities

*"Ensure that Europe has the supply of affordable medicines to meet its needs and support Member States in improving the quality and sustainability of their health systems"* (Mission letter to Commissioner-Designate Kyriakides)

- Affordability of medicines and health system sustainability
- Fighting shortages of medicines by ensuring access to innovative medicines and actual availability of marketed medicines
- Ensure legislation is future looking and flexible enough to reap the benefits of digitalisation
- Ensure oversight of the global manufacturing supply chain while addressing security challenges
- AMR
- Communication on vaccination
- Cancer Action Plan



# Responding to the needs

- Evaluation of orphan/paediatric legislation
- Implementation of medical device legislation
- Implementation of clinical trial legislation
- Optimisation of legislation
- Research funding

# Looking ahead as a network

- Continuous interaction with EMA and HMA
- Trilateral meetings
- Exchange about challenges and opportunities



# Outreach to Member States

Pharmaceutical Committee as a major hub for discussion

- **Working method**
  - Input may come from Commission, MSs, other fora
  - Possibility to hold joint meetings with other expert groups/stakeholders
  - Work on priorities grouped around common themes / work strands
- **Priorities**
  - Grouped around 3 themes: sustainable innovation, ensuring access and affordability while addressing shortages, unmet needs, ensuring security and oversight of the global manufacturing supply chain
  - Overlap with Commission's identified priorities



**More information:**

**<https://ec.europa.eu/health/human-use/>**