Regulatory Optimisation Group

An update

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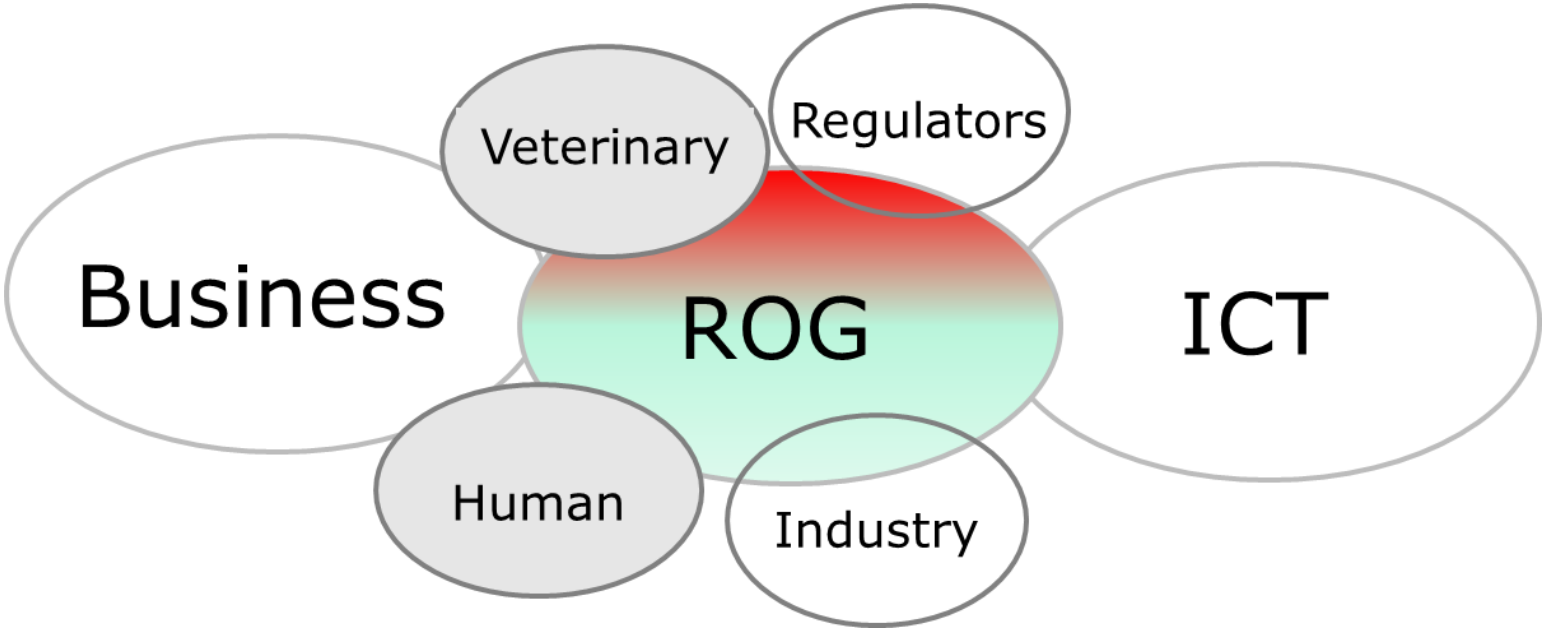
Medicines Evaluation Board

ROG = spin-off MAWP HMA priority 8



Regulatory Optimisation Group – an update (1)

- Founding principle is optimisation of regulatory work by:
  - Looking clever, open and innovative on our business models & processes
  - Taking away unnecessary (national) requirements
  - Taking away legal obstacles
  - Combine good ideas with good IT
  - Learn from each other, take over solutions
  - Cooperation with industry necessary
  - Human + Veterinary
  - HMA-group but participation/cooperation EMA
  - Etc.
- Initial approval of this group at June HMA in Rotterdam

Regulatory Optimisation Group – an update (2)

- Initial group formed: IRL, UK, EE, ES, FI, SE, AT, NO, EMA and NL
- Three TC's held + 1 FtF
- Activities so far:
  - Scope discussion (i.e. MAWP action item list)
  - Participation and skill-set (survey on business analysts capacity in the network)
  - Setting up virtual work-space
  - Organizing next steps (feedback HMA, CMD, TC's, FtF)
  - Initial feedback at HMA September Bratislava
  - Presentation at CMD September 2016
  - Face to face meeting Utrecht November 2016

Regulatory Optimisation Group – an update (3)

- HMA Feedback:
  - Clarify the remit of the group (including IT and business processes aspects)
  - The actions from the HMA MAWP should be allocated to the group
  - Membership (incl. the role of EMA)
  - this should primarily be a HMA group as it delivering the actions from the HMA MAWP, however there is scope for EMA can be involved as appropriate)
  - Should be broad enough to deliver its objectives and should include operational representatives

Regulatory Optimisation Group – an update (4)

- HMA feedback (continued)
  - Accountability and reporting arrangements:
    - With clear deliverables
    - Accountability should be to the priority lead (Hugo Hurts (MEB) and support (Ian Hudson (MHRA) for Optimisation of the regulatory network
  - Timeframes:
    - HMA MG saw this as a task force with a set end date
    - Outline of the milestones
- Alignment with the CMDx
- Need for formalisation: Terms of Reference

Regulatory Optimisation Group – an update (5)

- Compilation presentation HMA-IT Rotterdam
- IRL, SE and NL present
- CMD feedback:
  - Overall positive, but somewhat hesitant:
    - First time overview of IT developments like SPOR, CESP, etc.
    - Consequences for income of NCA’s
    - Consequences on legal issues
    - Developments not going too fast?
    - Role of CMD clear
  - Asked for participation from CMD in the next months

Regulatory Optimisation Group – an update (6)

- End-of-year deliverables:
  - ROG installed + profile membership
  - ToR finalised and agreed by HMA
  - FtF meetings
  - Concept work plan 2017 available

First informal Face-to-face Meeting – Day 1

- Regulators only
- ToR under construction, headlines:
  - Background and introduction
  - Definition of the mandate
  - Composition defined, including industry participation
  - Working approach
- Ideas gathering for work plan 2017

First informal Face-to-face Meeting – Day 2

- Regulators and industry (H+V)
- Information exchange
- Ideas gathering for work plan 2017
- Defining problem statements
- Problem statement + ideas connected (attention on immediate action)
- Message to HMA

ROG Process

- Problem identification
- Problem Prioritisation
- Business Case development:
- Business Case Submission
- Benefits Realisation Monitoring

Next steps

• Nov:	Approval ToR by HMA	HMA
• Nov – Jan:	Installation official ROG	MS
• Nov – Jan:	Concept work plan 2017	‘ROG’
• Dec:	Conference Call ‘ROG’	‘ROG’
• Feb:	Second F2F-meeting	ROG