Robust and objective scientific dialogue between government and stakeholder experts

An industry perspective

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Background?

The public discussion…

European Ombudsman; Strategic inquiry into EMA pre-submission meetings:

- …such activities may pose some risks, such as that the eventual decisions by EMA on the authorisation of medicines may be influenced by what has been discussed during the meetings with medicine developers…"
- Even if EMA were to ensure that its subsequent assessments […] are objective and complete, **there is still a risk that pre-submission activities create, in the eyes of the public, at least some perception of bias.**

Background?

The public discussion…

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BEUC comments on 'Open EFSA'

- To safeguard its independence and to remain credible to consumers, **EFSA needs to keep its distance from the food industry whose products it assesses.**
- **…face-to-face meetings between EFSA and each individual applicant should be prohibited** as they have the potential to increase pressure on scientific experts.
- **…it is very difficult to gather knowledge from stakeholders in practice without being influenced by their evaluations.**

Background?

The public discussion…

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Letter from associations representing EFSA regulated industries (2014)

- Should product specific pre-submission meetings between the notifiers and the evaluating group be undertaken, it is felt the **quality of dossiers would improve, especially for dossiers concerning innovative products.**
- Other regulatory agencies […] actively encourage applicants to ask for pre-submission meetings.
- *"The EMA emphasises the importance of scientific advice or protocol assistance pre-submission meetings with companies".*

Scientific and regulatory dialogue

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- **Dossier specific dialogue is not possible at the EFSA level**
  - Especially for PPPs - dialogue with RMSs only
- **More dialogue in other agencies / sectors / regions**
  - ECHA: REACH, Biocides, CLH
  - EMA: Human and Veterinary medicines
  - Third country agencies
  - National agencies – PPP authorisation

In most cases, dialogue is encouraged – WIN-WIN for authorities and industry

Robust and objective scientific dialogue *- Key elements*

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- **A need for the process to *communicate***
  - With those who '**want to know**' and who '**want to comply**'
- **A need for the process to *be challenged***
  - Focus on the assessment not assessors!
  - Request for more animal testing must be challenged!
- **A need for the process to *be inclusive***
  - Scientific dialogue (challenge?) with all interested parties
- **A need for the process to *be transparent***
  - Good communication on evaluation reasoning

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Scientific discourse between authorities, industry & NGOs

- ***ECPA support the need for discussions to involve all interested parties in regulatory process***
  - Appears to work in EMA & ECHA (e.g. RAC)
  - Industry wants to dialogue to understand the process and help ensure compliance (**want to comply**)
    - Supports the participation of other stakeholder (**want to know**)

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Risk assessment and risk management

- A robust system needs to involve all parties in the regulatory process.
- Separation between assessors and risk managers leads to **less transparency** and **poor communication**
  - Needs major improvements at the EU level
- What system works well? >> Single agency!
  - AGES Austria, EPA USA, PMRA Canada

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Guidance document development

- The development of EU guidance documents is causing major challenges in the evaluation process
- Initial input and active participation in the process has been restricted to a few people – which has contributed to the problem
- An inclusive process allowing a scientific and regulatory dialogue would be more robust
- The process would be more robust and objective by challenging the assumptions, e.g.
  - *Are changes needed? If yes, why ?*
  - *How to incorporate latest technical developments ?*
  - *Additional data needed ?*
  - *Should this issue be managed at national, EU or global level?*
  - *How to minimise animal testing?*
  - *Does the final document fulfil its objectives ?*
  - *Are the timelines feasible?*

What was the question?

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- We have talked about **A robust and objective scientific dialogue?**
- What we need is **Scientific dialogue for a robust and objective regulatory process**

Conclusion

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- **A need for the regulatory process:**
  - to communicate
  - to be challenged
  - to be inclusive
  - to be transparent
- **We need a scientific dialogue to support a robust and objective regulatory process**
  - Dialogue - to challenge the assessment not the assessor
  - Process robust and objective only if it is challenged
  - Differentiate between those who '**want to know**' and those who '**want to comply**'
  - But all stakeholders have a voice and should be heard

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THANK YOU