

EMA's approach to stakeholder engagement

EFSA's 3rd Scientific Conference - Engaging with Society

Presented by Melanie Carr Head of Stakeholder & Communication Division





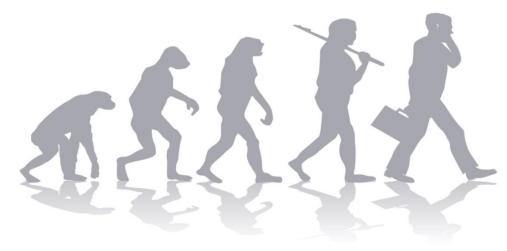
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EMA and its Stakeholders

The EMA has been interacting with its stakeholders on various levels since its creation.





Need for common principles, better coordination and streamlining?



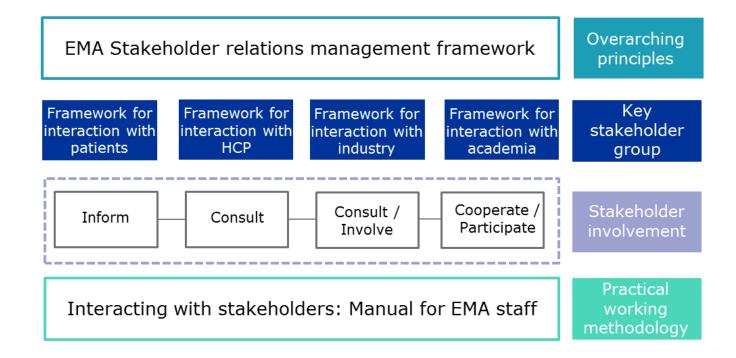
EMA Stakeholder engagement principles

Stakeholder interaction must be based on the fundamental principles:

- Transparency
- Independence and integrity
- Accountability
- Appropriate interaction
- Broad representation
- Effective communication
- Continuous improvement

EMA Stakeholder Relation Management Framework June 2016

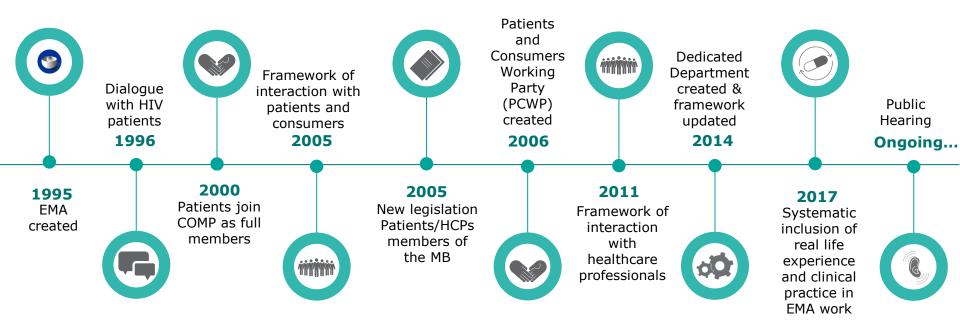
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	Although the level of interaction may vary, the Agency's overall management of stakeholder intera is based on the fundamental principles of:
	 transparency,
	 independence and integrity.
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Together, these building blocks ensure a **consistent approach to stakeholder relations management** across a variety of stakeholder groups and interaction types.



Patients, consumers and health professionals A long journey...





Framework and working party



Healthcare Professionals" Working Party (HCPWP)

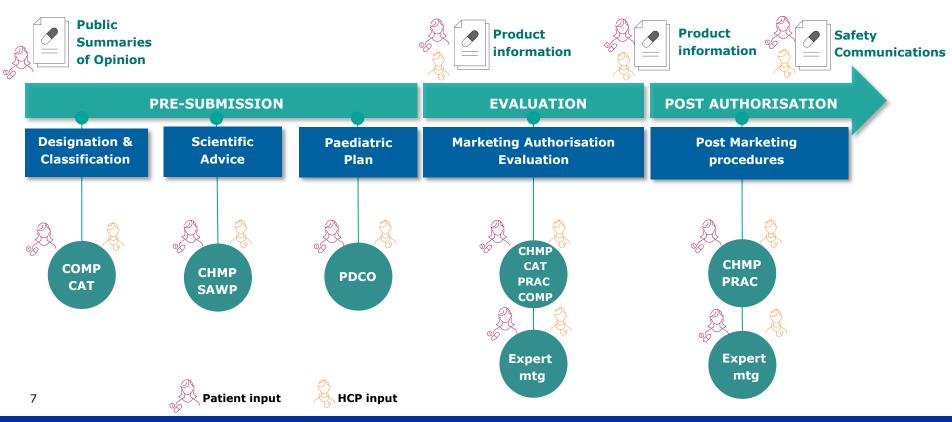




Patients' and Consumers' Working Party (PCWP)



Involvement along the medicine lifecycle at EMA





What support and resources are available?





Engagement methodologies; a menu of options is needed



Public hearing

A new tool to get input from the public during a EU safety review Usually focused on risk minimisation measures

So far 2 public hearings valproate and quinolones



First public hearing on Valproate

Held on **26 September 2017**, in the context of a safety review to reduce the risks of valproate medicines in pregnancy.

Outcome of public hearing was <u>instrumental</u> in recommending new measures to avoid exposure of babies to valproate in the womb:

- further restrictions on the use of valproate in women
- a new pregnancy prevention programme
- a new risk acknowledgement form
- a visual warning in the outer packaging



Impact on the assessment and added value

- **Consultations** with patients and health professionals laid at the **core of valproate safety review**
- Hearing helped to **identify the real problems** in clinical practice
- Provided valuable insight and information which <u>otherwise would have not been provided</u>
- Contribution shaped the second part of the assessment and identified the questions for the expert meeting (SAG)
- Input used directly for the **final recommendations**



Overall feedback received from **all parties** shows **first hearing** can be considered a **success**

Well conducted with optimal timing / Relevant and valuable contributions

79% of PRAC members

said that it would

`make a difference to the assessment of Valproate'

88% of participants

said they felt that the public hearing

`would make a difference to the Committee recommendations'



Lessons learnt after first experiences

- Public hearing adds value, improves quality of the assessment and foster trust in the system:
 - It led to better safety recommendations, tailor to meet the real needs and problems of patients - identified at the hearing
 - It allowed different stakeholders **to listen to and learn** from each other
 - It increases overall transparency and understanding of regulatory procedures in Europe
- Organisational aspects successful experience recommendations from lessons learnt to be implemented
- Resource intensive tool decision to hold a hearing needs to be well balanced



Conclusions The value of public engagement



TRUST + BETTER OUTCOME



Thank you for your attention

Further information

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