

### EMA's approach to stakeholder engagement

EFSA's 3rd Scientific Conference - Engaging with Society

Presented by Melanie Carr Head of Stakeholder & Communication Division





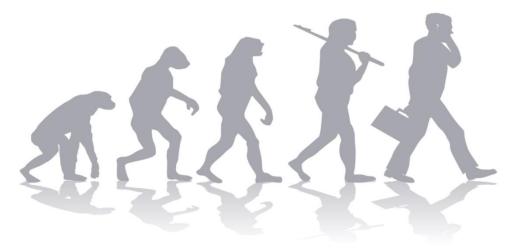
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### EMA and its Stakeholders

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





### Need for common principles, better coordination and streamlining?



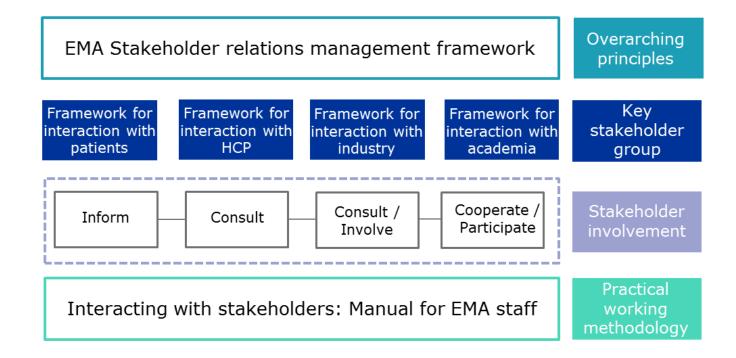
### EMA Stakeholder engagement principles

## 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

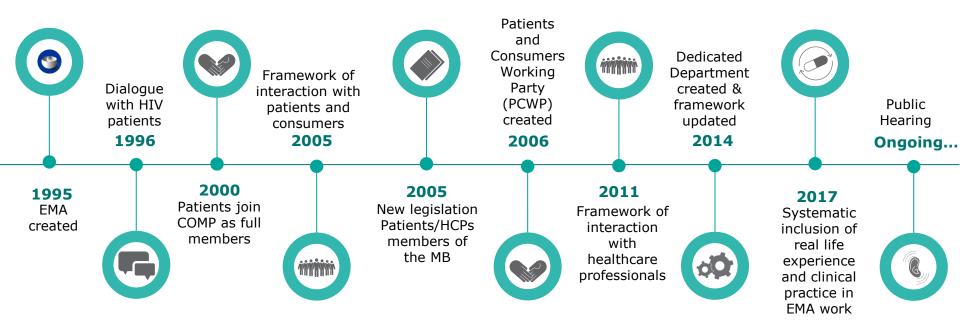
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|  | Although the level of interaction may vary, the Agency's overall management of stakeholder intera<br>is based on the fundamental principles of:   |
|  | <ul> <li>transparency,</li> </ul>   |
|  | <ul> <li>independence and integrity.</li> </ul>   |
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|  | <ul> <li>appropriate interaction,</li> </ul>  |
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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)

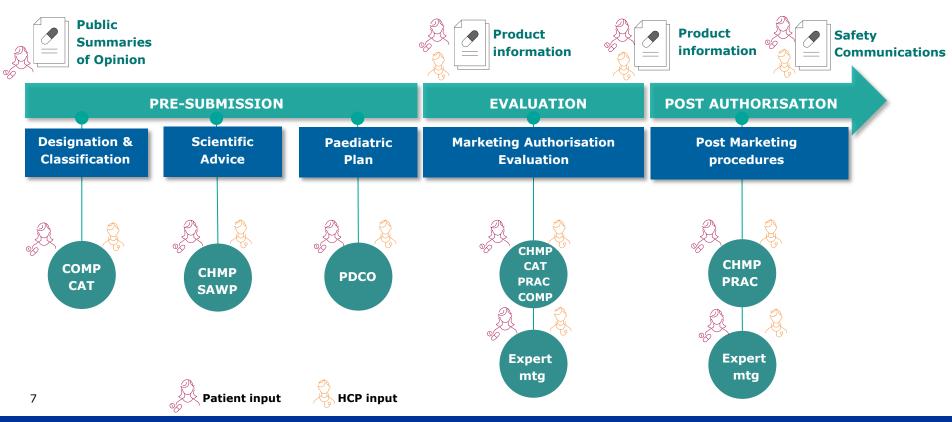




Patients' and Consumers' Working Party (PCWP)



### 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

Contact me at Melanie.Carr@ema.europa.eu

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