



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA's approach to stakeholder engagement

EFSA's 3rd Scientific Conference - Engaging with Society

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An agency of the European Union





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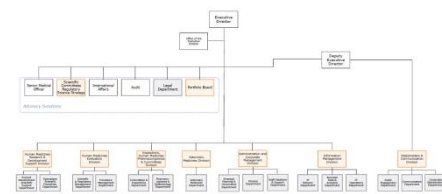
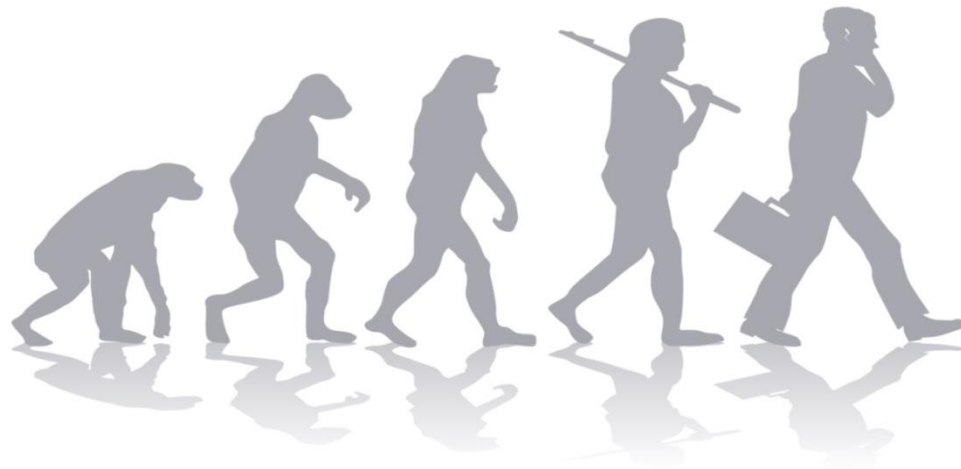
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EMA and its Stakeholders

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



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

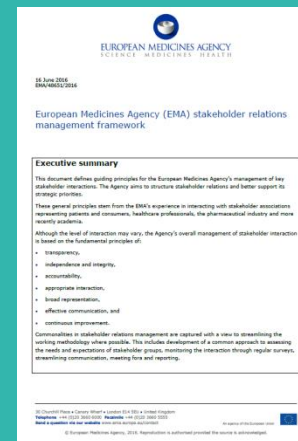


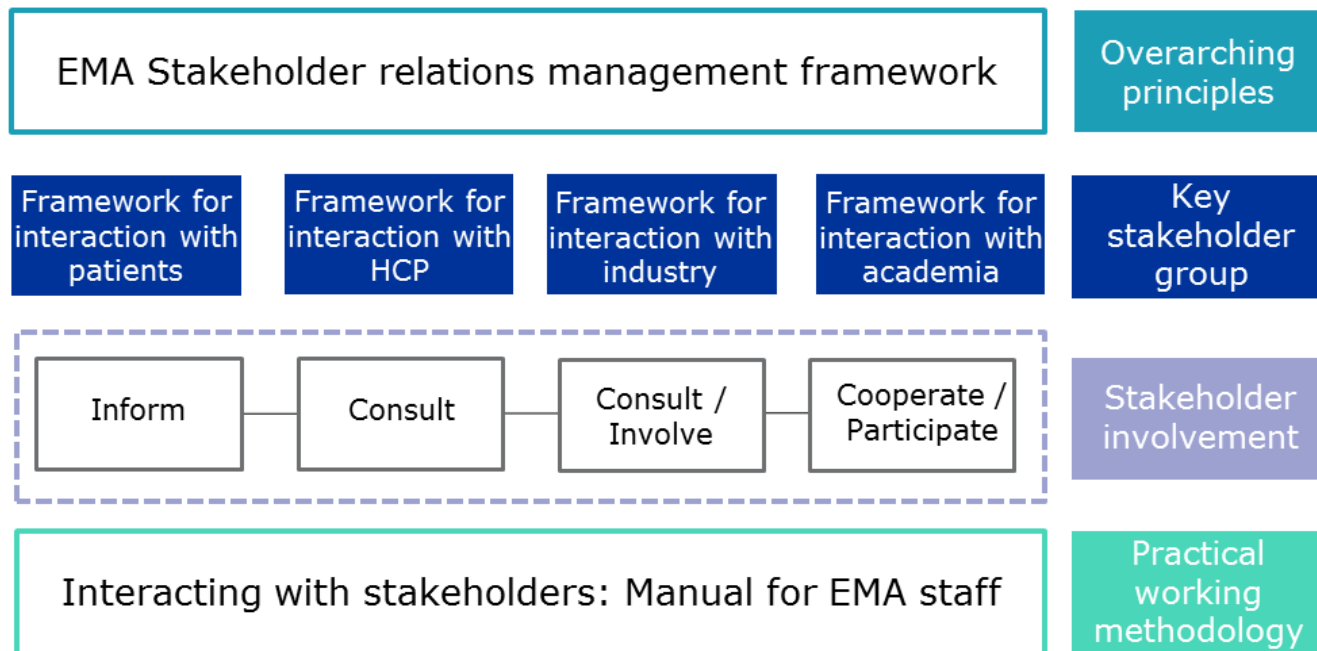
EMA Stakeholder engagement principles

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



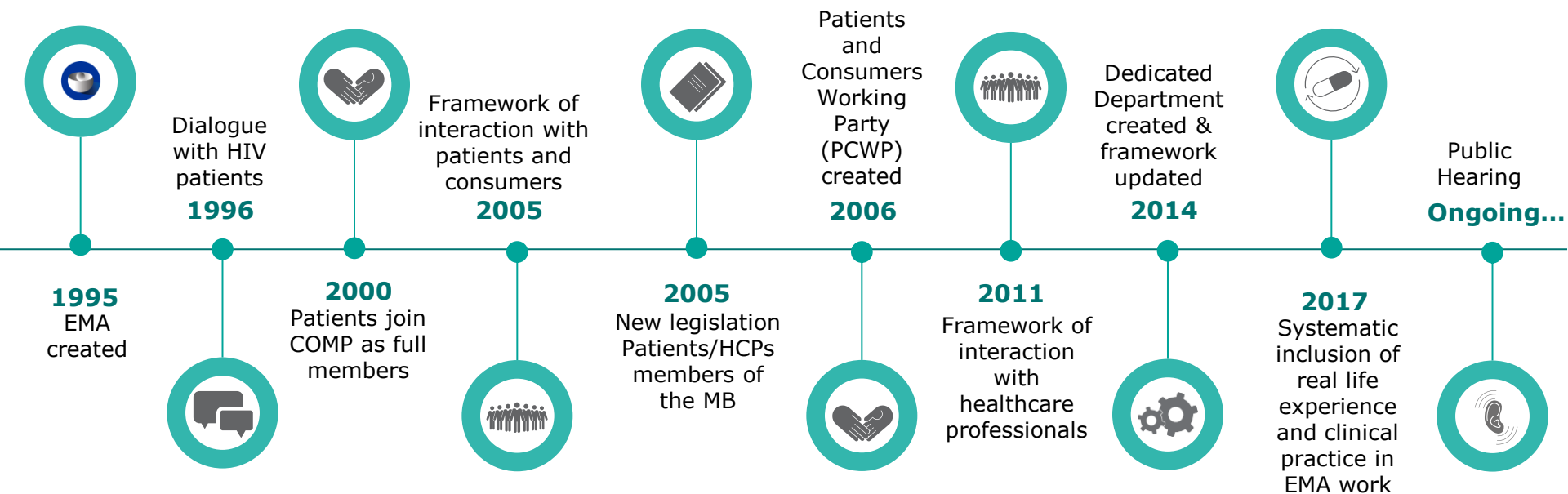


Together, these building blocks ensure a **consistent approach to stakeholder relations management** across a variety of stakeholder groups and interaction types.



Patients, consumers and health professionals

A long journey...





Framework and working party

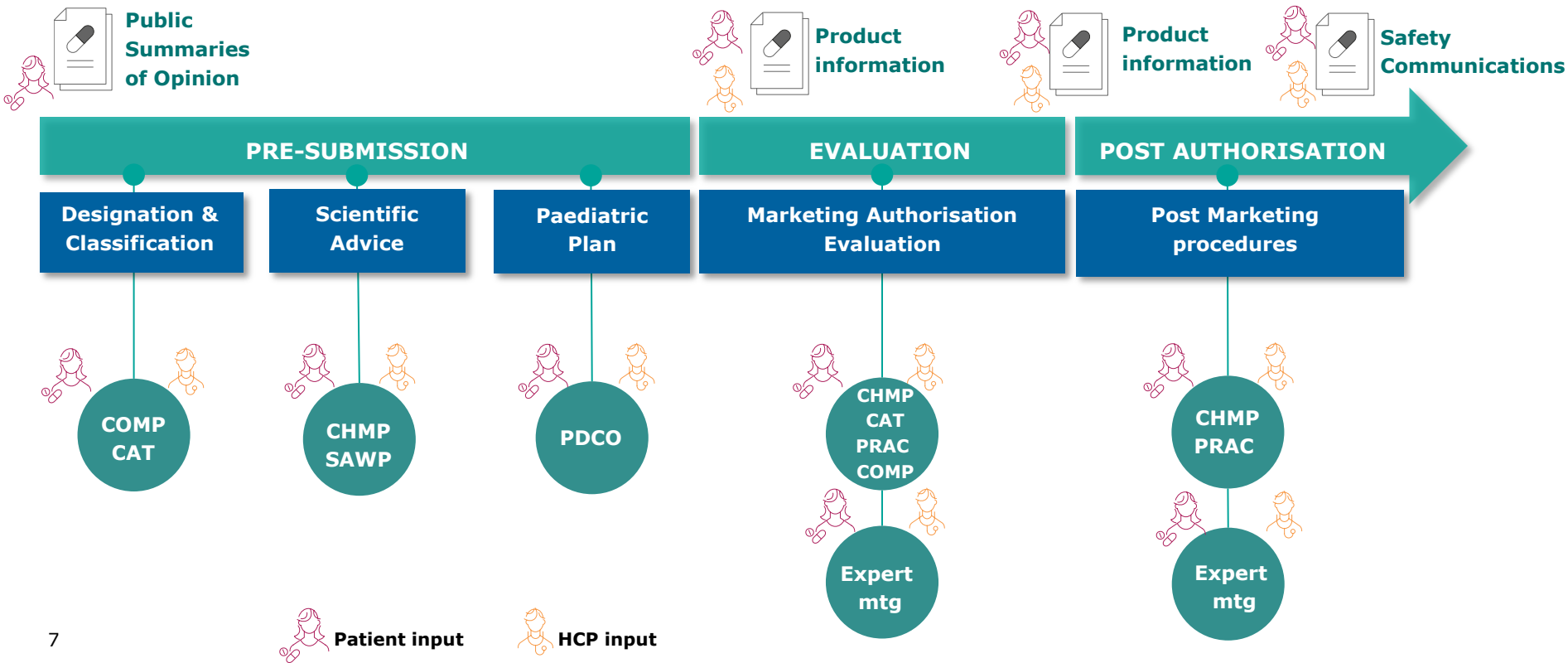


Healthcare Professionals' Working Party (HCPWP)



Patients' and Consumers' Working Party (PCWP)

Involvement along the medicine lifecycle at EMA



What support and resources are available?



Annual training day



Videos; EMA basics



Info-sheets



One-to-one personalised support



Webpages

Engagement methodologies; a menu of options is needed

One size does not fit all!



Public hearing

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

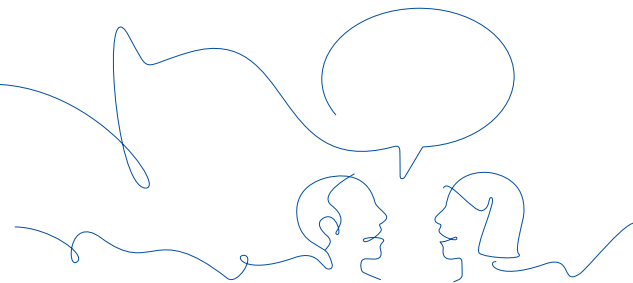
So far 2 public hearings
valproate and **quinolones**

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 instrumental in recommending new measures to avoid exposure of babies to valproate in the womb:

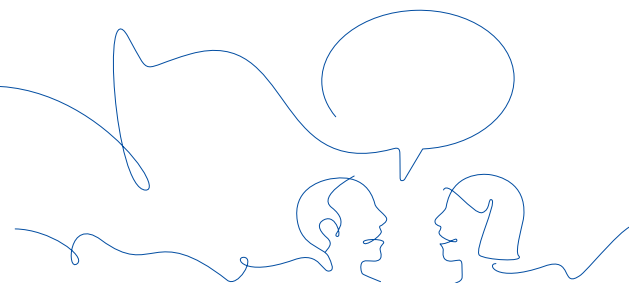
- further restrictions on the use of valproate in women
- a new pregnancy prevention programme
- a new risk acknowledgement form
- a visual warning in the outer packaging





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 otherwise would have not been provided
- 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

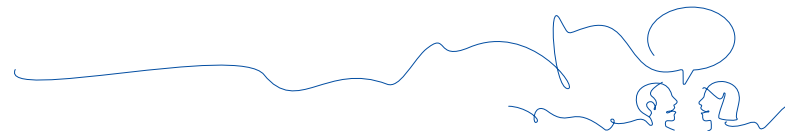
said that it would

'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



Involving
patients and
healthcare
professionals



Transparency



Efforts in
communicating
openly

TRUST

+

BETTER OUTCOME



Thank you for your attention

Further information

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