EMA’s approach to stakeholder engagement

EFSA’s 3rd Scientific Conference - Engaging with Society

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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
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...

1995  EMA created
1996  Dialogue with HIV patients
2000  Patients join COMP as full members
2005  Framework of interaction with patients and consumers
       New legislation
       Patients/HCPs members of the MB
2006  Patients and Consumers Working Party (PCWP) created
       Systematic inclusion of real life experience and clinical practice in EMA work
2005  Dedicated Department created & framework updated
2011  Framework of interaction with healthcare professionals
2014  Ongoing...
2017  Public Hearing
       Systematic inclusion of real life experience and clinical practice in EMA work

EMA’s approach to stakeholder engagement
Framework and working party

Healthcare Professionals’ Working Party (HCPWP)

Patients’ and Consumers’ Working Party (PCWP)
Involvement along the medicine lifecycle at EMA

**PRE-SUBMISSION**
- Designation & Classification: COMP CAT
- Scientific Advice: CHMP SAWP
- Paediatric Plan: PDCO

**EVALUATION**
- Marketing Authorisation Evaluation: CHMP CAT PRAC COMP
- Expert mtg

**POST AUTHORISATION**
- Post Marketing procedures: CHMP PRAC
- Expert mtg

- Public Summaries of Opinion
- Patient input
- HCP input
- Safety Communications
- Product information
What support and resources are available?

Annual training day

Webpages

Videos; EMA basics

Info-sheets

One-to-one personalised support
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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