European Federation of Pharmaceutical Industries and Associations

Listening to the public – valproate case history
-- *industry's perspective on the public hearing*

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Organization of public hearing

First public hearing of the EMA, which the industry supports in principle, provided such hearings are balanced and structured.

- Well organized with clear communication on the event, widely disseminated in advance
- Focused and concise questions posed by PRAC
- Wide range of stakeholders given opportunity to participate
- Sufficient time given (prior to public hearing) to participants to prepare

Public hearing fostered atmosphere of transparency and provided a forum for stakeholders to communicate their views in public

Public hearing: MAHs' perspective

Empathize with individual experiences, acknowledging the difficulties faced by patients and families

- According to regulations, MAHs are not allowed to directly communicate with patients.

- Public hearing was an opportunity also for MAHs to listen to patients, and to take into account patients' views in making proposals

Public hearing: practical considerations

A fair representation from all stakeholders is important to balance emotions and personal experiences with scientific data

- **16 speakers** (representatives from patients/family, healthcare professionals, academics, one MAH representative)
- Suggestions:
  - **Broader participation** (from more member states, more MAHs)
  - **Allocation of time** (consider more than 7/112 minutes for MAH who holds dataset)
  - **Order of speakers** could be re-arranged to group together data from MAH and academics
  - **Seating arrangement** could be re-organised to minimize pressure on some speakers
  - **Management of speakers and question time**
    - Some observers and speakers spoke without regard to the original questions posed
    - Some observers took too much time for interventions during question time

Public hearing and additional RMMs

- Public hearing contributed opinions and perspectives to the effectiveness of existing risk minimization measures and new measures (questions 2 & 3 posed by the PRAC)
  - E.g. Outerbox warning and pictogram
- Public hearing contributed to thinking on research
  - E.g. registry study on switching and discontinuation
- Due to different decision-making at national level, aRMMs may not be implemented or implemented differently, therefore may not meet the expectations of some members of the audience at the public hearing
  - E.g. pictogram
- Public hearing could lead to expectation that changes would be visible very soon; although due to regulatory procedure, it often took longer to implement
- Public hearing might have led to pressure and unrealistic timelines
  - E.g. timelines for PASS and pre-clinical studies, which are part of the MA conditions, are too tight

Public hearing and on-going procedure

- Public hearing led to public pressure on competent authorities of certain member states.
  - **Widespread coverage in the media in some member states including national TV**

- Some competent authorities took unilateral action while the procedure was on going, e.g.
  - **Local initiative to change the national labelling**
  - **Requests for educational materials to be submitted before the end of the referral; and for reduced packaging size**

- While good intentions are acknowledged, these posed challenges to MAHs because of discrepancies of the information to patients and HCPs across countries

Public hearing – conclusion & discussion

- Success in advancing the broad objective of engagement with the public
- Contributed to views on effectiveness of existing RMMs and ideas on additional RMMs and research
- Need to better balance testimonies/personal experience and scientific data contributed by different stakeholders
- Time from public hearing to changes visible to public could be long
- Main objective of an Art. 31 referral is to harmonise information across EU
  - Public hearing could inadvertently create pressure on some competent authorities to take unilateral actions, which might have led to divergent labelling
  - Lack of harmonization for some RMMs makes the implementation difficult and could complicate the analysis of the effectiveness of these RMMs