
C B G
M E B

Involving patients and healthcare professionals in regulatory decisions – MEB experience

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Composition of the MEB

- the Medicines Evaluation Board has a maximum of seventeen members, including the chairman

- the members are medical specialists, hospital pharmacists, professors and other experts who fulfil the position of MEB members alongside their primary position

Healthcare professionals

- The MEB consists of 17 healthcare professionals

- In addition, since 2009 the MEB meets with healthcare professionals on a regular basis (± 3 times each year) → Medical Practice Expert Group
- Since 2013: minutes of these meetings are published on the MEB website

Objectives of these meetings

- Receive and provide feedback on medicine use aspects in daily practice, in terms of both the information provided and the medicine itself

Healthcare professionals

- Identify problems in daily practice, such as product withdrawals, abuse or incorrect use of medicines, product availability, packaging and administration issues, product information

- Identify problems with substitution of generics and biosimilars

- Discuss medication errors where MEB could take action, e.g. by improved user instructions or label modifications.

Patient and consumer organisations

- Since July 2004, the MEB meets with patients and consumers organisations on a regular basis (± 3 times each year)
- Minutes are published on the MEB website

- Discussions regarding
  - General issues, e.g. communication
  - On-going procedures are not discussed
  - Clarification on regulatory decisions after a final decision
  - Clinical guidelines
  - Issues regarding product information (braille, readability test)
  - Regulatory developments, e.g. PRAC

Patient and consumer organisations

- First pilot early 2013: all participants were invited to attend one or two Board meetings
- Confidentiality agreement: access to all assessments reports and documents and attend also the closed part of the meeting
- Goal: increase transparency, to give an insight in the discussions

Feedback from 1st pilot

- To provide input on all agenda items is not possible: could it be limited to the own pharmcotherapeutic area → this has practical limitations

- It is possible to provide input regarding
  - General issues
  - Guidelines
  - Communication regarding safety issues
  - Risk minimisation activities

2nd pilot – currently on-going

- Patients and consumers will attend part of the Board meeting:
  - General issues
  - Guidelines
  - PRAC procedures (emphasis on communication)

- Input and active participation is requested

And …

- The MEB is investigating possibilities to get input from patients and consumers outside Board meetings:
  - Product specific issues
  - Product information
  - Educational material
  - User-friendliness
  - Communication, DHPC


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