Patient involvement at the MEB

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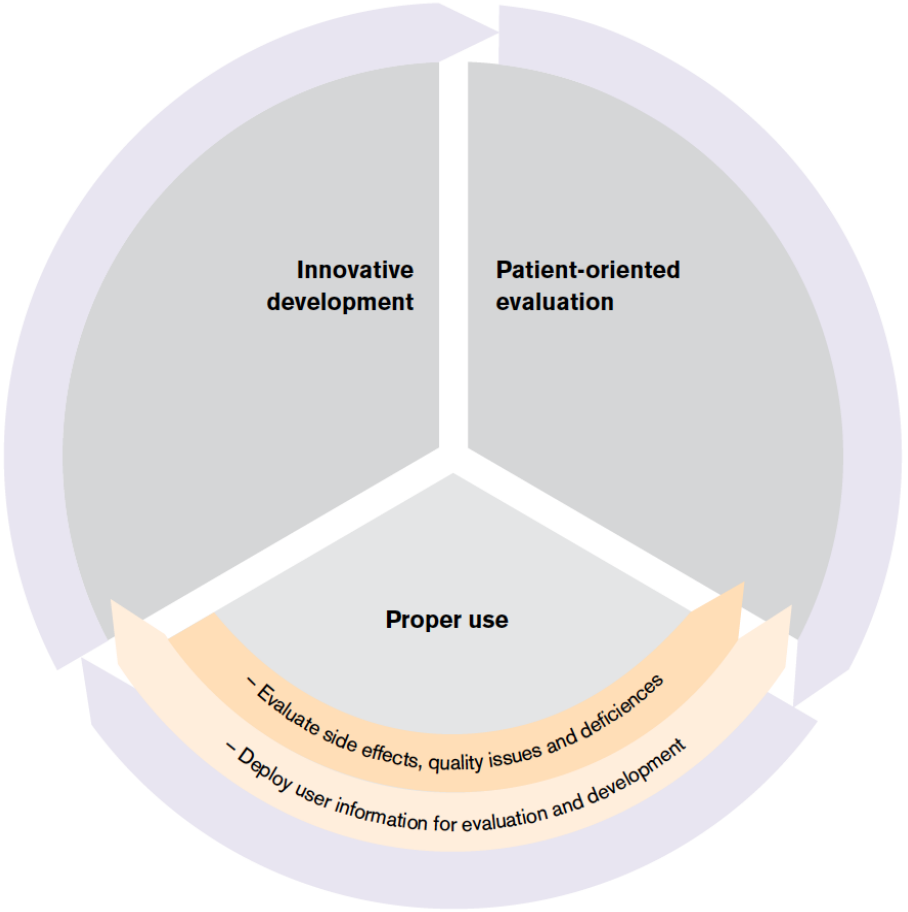
Strategic Business Plan of MEB 2014-2018

- Focus on the entire **life cycle** of a medicinal product
- **Patient** is most important stakeholder
- Aim: Receive input from patients to strengthen the connection to the user's practice
- Transparency on how MEB operates and create support for regulatory decisions



Currently at MEB

- Since 2004 “Overleg CBG patiënt en consument”
  - 3-4 times per year
  - Minutes published on the MEB website
  - Different subjects discussed: clinical guidelines, issues with product information (braille, readability text), regulatory developments (e.g. PRAC), clarification of regulatory decisions, general subjects (e.g. communication)

- Theme-meetings: biosimilars, information provision
- Goal: Inform → Inform and consult
- Questions from (individual) patients
- A list of patient organisations:
  - to inform on decisions,
  - request for input on decisions/questions
  - (e.g. Thyrax, medicinal products for ADHD, in case of suspensions)

Patient involvement in decision making process

- 2013-2014: Pilot on presence of patient representatives during the Board meetings
- Since 2015 – Annemiek Rensen - Board member on patient- and consumer-perspective

Patient organisations consulted for guidelines

1) Concept paper on the need for revision of the points to consider on the clinical investigation of new medicinal products for the treatment of **acute coronary syndrome** (De Hart & Vaatgroep)

2) Draft qualification opinion of qualification of exacerbations 5 of chronic pulmonary disease tool (EXACT), and EXACT-6 respiratory symptoms measure (E-RS) for evaluating 7 treatment outcomes in clinical trials in **COPD** (Longfonds)

3) Risk minimisation strategy for high strength and fixed combination insulin products Draft addendum to the good practice guide on risk minimisation and prevention of medication errors (Diabetesvereniging Nederland)

4) Guideline on clinical investigation of medicinal products other than NSAIDs for treatment of rheumatoid arthritis (Reumafonds)

Future

MEB wants to strenghten the connection with patient organisations, and involve patients earlier in the decision making process

- Regulatory guidelines
- Scientific Advice
- Risk Communication Material
- Theme meetings on a specific disease area

Consultation with patient and consumer organisations

http://english.cbg-meb.nl/human/for-patients-and-consumers

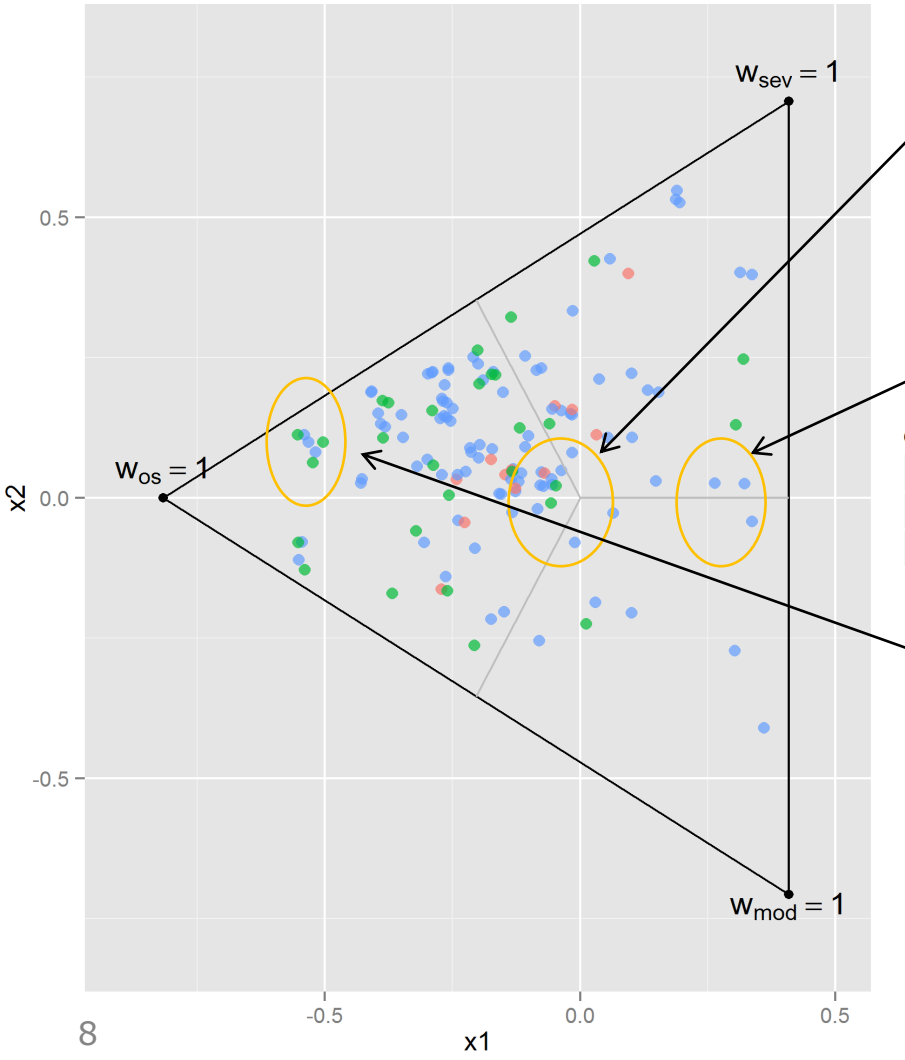
Revised framework of EMA interaction with patients

- In December 2014, the EMA Management Board adopted a revised framework of EMA interaction with patients, consumers and their organisations to reach out to a wider audience

- One of the objectives of the framework is **to facilitate participation of patients and consumers in benefit/risk evaluation**

- A number of methodologies are available, from informal methods (expert opinions) to **more formal methods (little experience so far)**

Distribution of the individual preferences



Centroid: all three criteria are equally important

Reducing toxicity is far more important than improving survival. Both toxicities are about equally important

Overall survival >> severe toxicity >> moderate toxicity

Conclusions

- Preliminary learnings
  - It is possible to use “rapid methods” to elicit patient values
  - Larger sample sizes are required to take into account demographic and clinical covariates
- Next steps:
  - Conduct a second pilot study

Acknowledgments:

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Innovative medicines faster available for the (Dutch) patient at a socially acceptable price

Thank you!