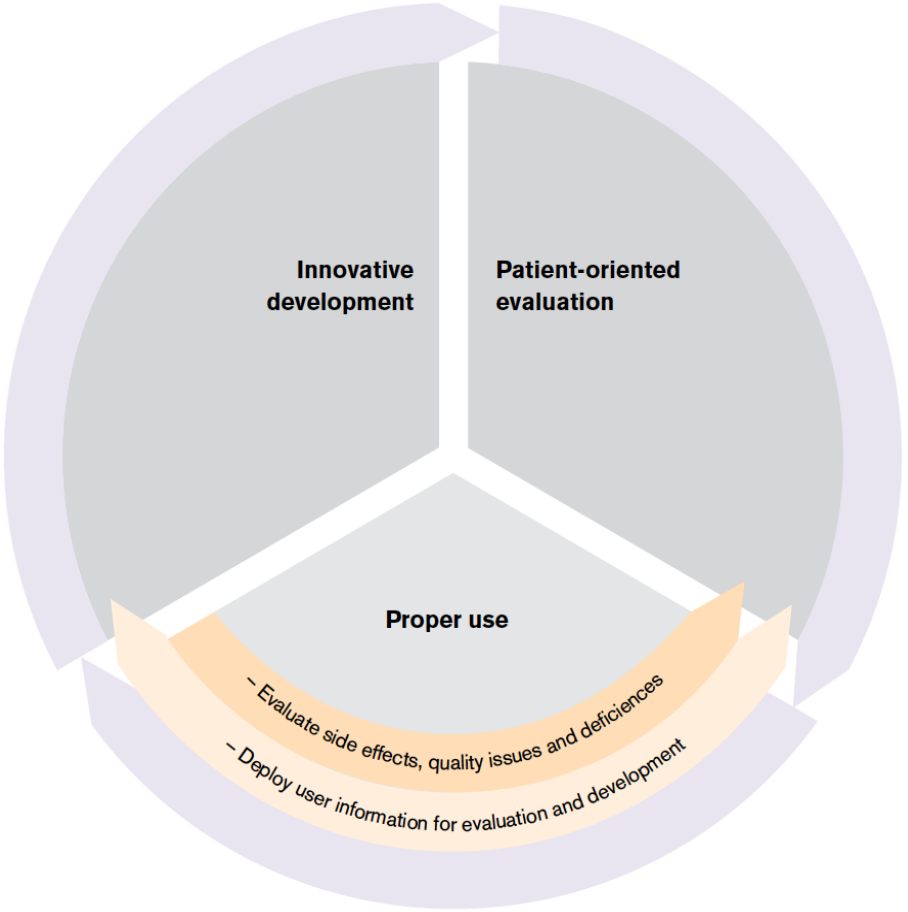
Patient involvement at the MEB

Violeta Stoyanova, MD, PhD, MPH
COMP member NL
Medicines Evaluation Board

EURORDIS summer school 2017
Barcelona

Strategic Business Plan of MEB 2014-2018

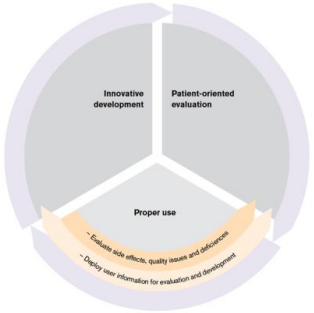
- Focus on the entire **life cycle** of a medicinal product
- **Patient** is most important stakeholder
- Aim: Receive input from patients to strengthen the connection to the user's practice
- Transparency on how MEB operates and create support for regulatory decisions



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 and regulatory 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 and consult
- Questions from (individual) patients
- A list of patient organizations:
  - to inform on decisions,
  - request for input on decisions/questions
  - work together in case of specific incidents (e.g. Thyrax, medicinal products for ADHD, suspensions)
- Since 2015 –Board member on patient- and consumer-perspective
  - Annemiek van Rensen - Senior advisor PGO support (patient and handicap organizations in NL)

Patient organisations consulted for guidelines



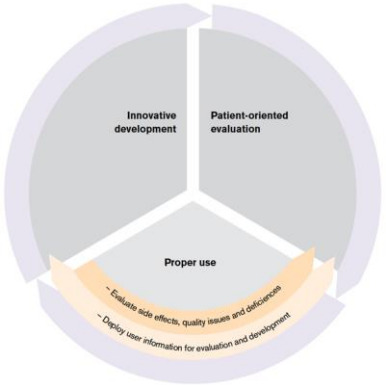
1) Concept paper on the need for revision of the points to consider on the clinical investigation of new medicinal products for the treatment of **acute coronary syndrome** (De Hart & Vaatgroep)

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)

Revised framework of interaction with patients



Since 1 Januari 2017 –portal:

'Passend regulieren'
Flexible reguatory thinking
science
evidence
patients' preferences

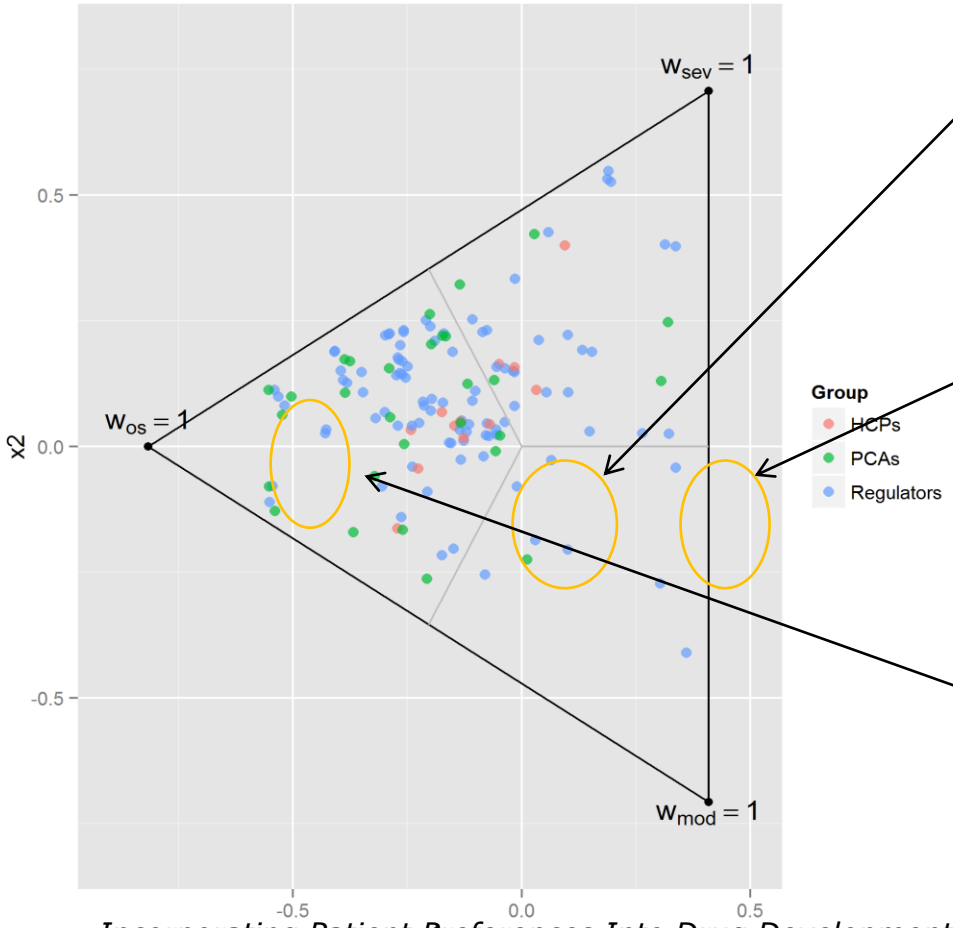
Consultation with patient and consumer organisations
http://english.cbg-meb.nl/human/for-patients-and-consumers

Availability of medicines:
Reporting of shortages
Defects
(In 2016 – important issue – shortage of Thyrax)
MEB – coordination of the information to patients and consumers
Patient organisations
Physicians and pharmacists organisations.

I-vision MEB


CLICK HERE
SPELD
MIJN CBG
selfservice portaal
Duurzaam toegankelijke informatievoorziening
Intelligente informatieanalyse
Actuele en accurate (geneesmiddelen)informatie
Ontsluiten van informatie voor goed gebruik
Selfservice portaal voor bedrijven

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

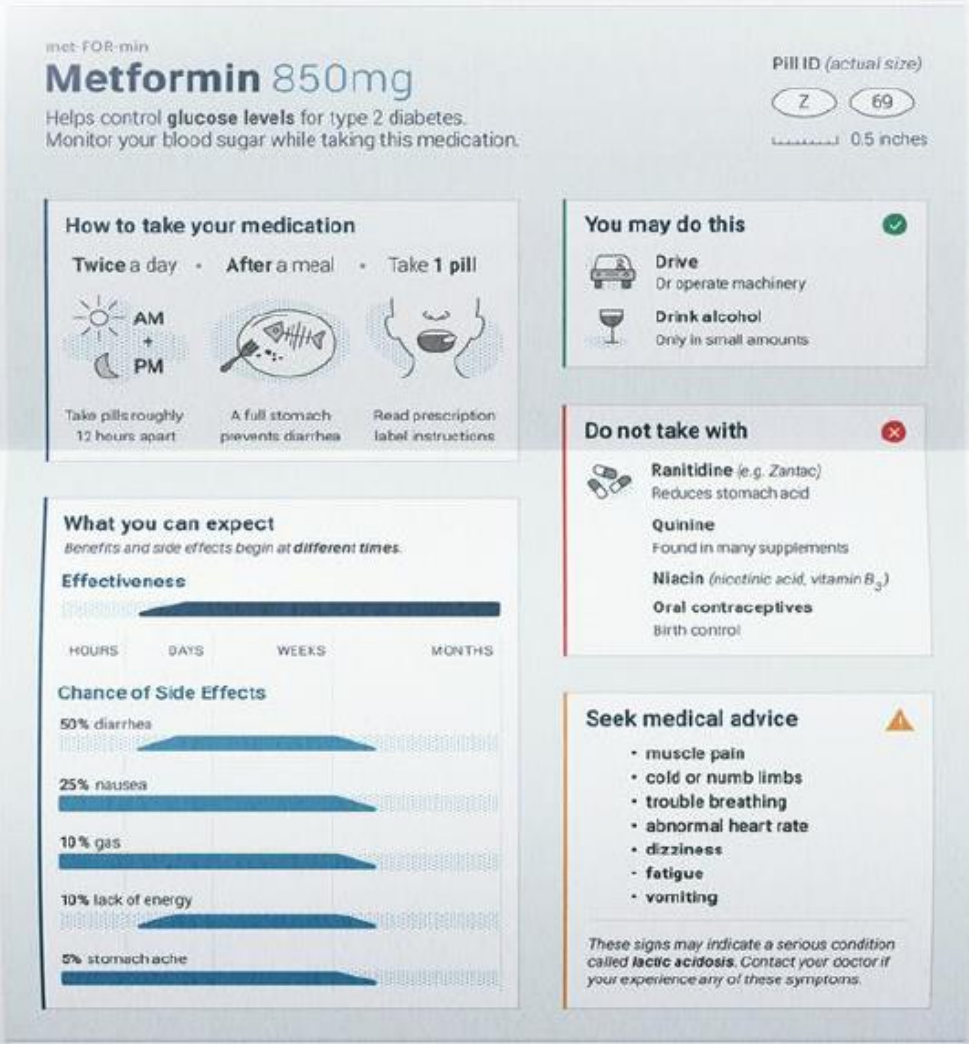
Incorporating Patient Preferences Into Drug Development and Regulatory Decision Making: Results From a Quantitative Pilot Study With Cancer Patients, Carers, and Regulators
D Postmus1,2, M Mavris1, HL Hillege2, T Salmonson1,3, B Ryll4, A Plate5, I Moulon1, H-G Eichler1, N Bere1 and F Pignatti1

The elicitation of individual patient preferences may lead to the **identification of subgroups with homogeneous preferences** and, as a result, to **market authorization decisions that are tailored to such subgroups**.

It may also highlight situations where the **regulators' value judgments** differ from those of **patients** and where there is greater need for **transparent and accessible communication** about the regulators' reasons and rationales that contribute to their decision.

Incorporating Patient Preferences Into Drug Development and Regulatory Decision Making: Results From a Quantitative Pilot Study With Cancer Patients, Carers, and Regulators
D Postmus1,2, M Mavris1, HL Hillege2, T Salmonson1,3, B Ryll4, A Plate5, I Moulon1, H-G Eichler1, N Bere1 and F Pignatti1

The PIL – even more patient friendly?



Questions for efficacy data registries

General design and objective of the registry

Population – eligibility and selection of patients

Intervention group and control or comparator group(s)

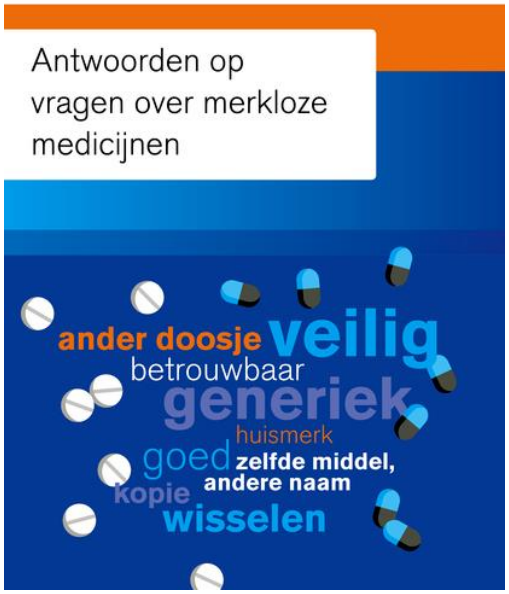
Endpoints – efficacy (and safety)

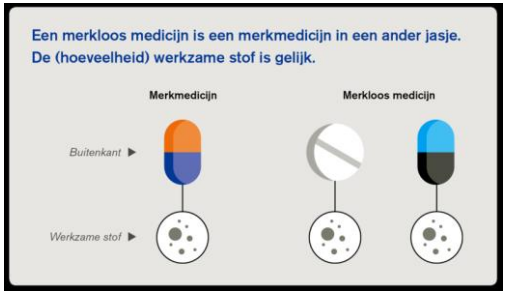
Data collection, quality and missing data

Method of analysis and presentation of results

Plans for communication of study results

Information prepared for and by the patients





Iedereen die een medicijn gebruikt moet daarop kunnen vertrouwen.
Dit is waar het College ter Beoordeling van Geneesmiddelen elke dag
aan werkt, in Nederland en in Europa. Goede medicijnen goed gebruikt.
College ter Beoordeling van Geneesmiddelen

Deze folder is opgesteld in samenwerking met:
- BijnierNET
- Consumentenbond
- Dutch Brain Council
- Longfonds
- Oogvereniging
- Patiëntenfederatie Nederland
- Nationale Vereniging ReumaZorg Nederland
- Nederlandse Hypofyse Stichting
- Schildklier Organisatie Nederland
- Stichting Borderline

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

Thank you!