COLLEGE

TER BEOORDELING VAN

GENEESMIDDELEN

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MEDICINES

EVALUATION

BOARD

CBG
MEB

EMEA/CPMP working group with patients' organisations

dr. Frits Lekkerkerker

co-chairman group

CPMP member

chairman Dutch Medicines Evaluation Board

EMEA/CPMP working group with patients' organisations

welcome

restart of discussions between EMEA / CPMP and consumer / patients organisations

EMEA/CPMP working group with patients' organisations

Topics I will address

- responsibility of the EMEA/CPMP
- why we have this meeting
- how and with whom
- topics to be discussed during working group meeting

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Topics to be addressed

- ↗ general topics patient related
- ↗ not specific product related

Why we organise this meeting

- ↗ to improve our patient orientated information
- ↗ not on political grounds

EMEA/CPMP working group with patients' organisations

Tasks of the EMEA / CPMP

- registration of medicines
- pharmacovigilance
- product related information
- transparency and information

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Tasks of the EMEA / CPMP

versus

Tasks of the national registration authorities

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Tasks of the EMEA / CPMP

- centralised marketing authorisations
- co-ordination pharmacovigilance
- referrals to the CPMP in case of disagreement MS

Tasks of the national registration authorities

- national marketing authorisations
- pharmacovigilance

Tasks of the EMEA / CPMP

- registration of medicines
  - after careful evaluation of benefit/risk ratio
  - after evaluation of quality
- pharmacovigilance
- product related information
- transparency and information

Tasks of the EMEA / CPMP

- ↗ registration of medicines
  - after careful evaluation of benefit/risk ratio
  - after evaluation of quality
- ↗ scientific role of the CPMP with

30 members from the EU countries

  - after initial evaluation of the dossier by two rapporteurs supported by national evaluation teams

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Tasks of the EMEA / CPMP

- registration of medicines
- pharmacovigilance
- product related information
- transparency and information

Tasks of the EMEA / CPMP

- registration of medicines
- pharmacovigilance
- product related information
  - Summary of Product characteristics (SPC)
  - European public Assessment Report (EPAR)
  - Patient Information Leaflet (PIL)
- transparency and information

Tasks of the EMEA / CPMP

- ↗ product related information
  - Summary of Product characteristics (SPC)
  - European public Assessment Report (EPAR)
  - Patient Information Leaflet (PIL)
- ↗ *the same SPC and PIL in all languages*
  - text is uniform
  - translation problems
- ↗ *EPAR in English*

what users want

- ↗ PILs should be ‘patient focussed’
- ↗ easily understandable
- ↗ more about the benefit
- ↗ less about all the side effects

Tasks of the EMEA / CPMP

- registration of medicines
- pharmacovigilance
- product related information
- transparency and information
  - transparency of the procedures
  - general background information

*partners for **EMEA / CPMP***

- industry
- doctors and pharmacists
- patient / caregiver
- citizens / community in general

why this group

improve

- ↗ communication to and from patients / citizens
- ↗ information to patients
- ↗ proper use of medicines
- ↗ safe use of medicines

why we should communicate

- ↗ a patient's right to know
- ↗ informed choices
- ↗ changing behaviour when taking medicines
  - reduce risks
  - maximise benefits

Therefore communication with patients is a key in the good use of medicines

why this group

improve

- ↗ our working practices
- ↗ our information documents
- ↗ our transparency

how to communicate and with whom

- patient organisations
  - general patient organisations
  - disease specific organisations
- consumer organisations
- only organisations on an European level
- no national organisations

with whom to communicate

- patient organisations
  - *how to identify the right partners*
  - *partners with good communication with their own organisation and the national organisations they represent*
  - *how to get independent partners*

with whom to communicate

- ↗ patient organisations
  - *a constant challenge is to find appropriate representatives of "patients" to take part in policy discussions,*
  - *e.g. most patient groups are specific to one condition or culture*

with whom to communicate

- ↗ *need for active partners*
- ↗ *need for proper representation*
  - how to get them

with whom to communicate

- invited organisations
  - BEUC Bureau Europeen des Unions de Consommateurs
  - EATG European AIDS treatment group
  - EFNA European Foundation of Neurological Association
  - EPHA European Public Health Alliance
  - European Cancer Leagues
  - Eurordis European Organisation of rare Disorders
  - IAPO International Alliance of Patients Associations
  - EMSP European Patients' Forum

how to communicate

how to communicate

- ↗ to give information
- ↗ to ask the right questions
- ↗ to listen to patient organisations
  - need for active partners
  - need for proper representation

information to patients

- ↗ timely and on going
  - patients need different types of information at different time points
- ↗ relevant (language/culture, lifestyle, interest)
  - significant cultural differences across Europe affects what patients expect
  - patients should be involved in the design of information provision to address their needs

information to patients

- high quality
  - transparent - understandable
  - reliable - evidence based
- accessible - just in time
  - at point of care
  - when information is needed
- right format
  - one size does not fit all

information to patients

- Patient Information Leaflet (PIL)
- via healthcare professionals
- via patient organisations
- via the web
- via the media

We as regulators have the most direct control over PILs.

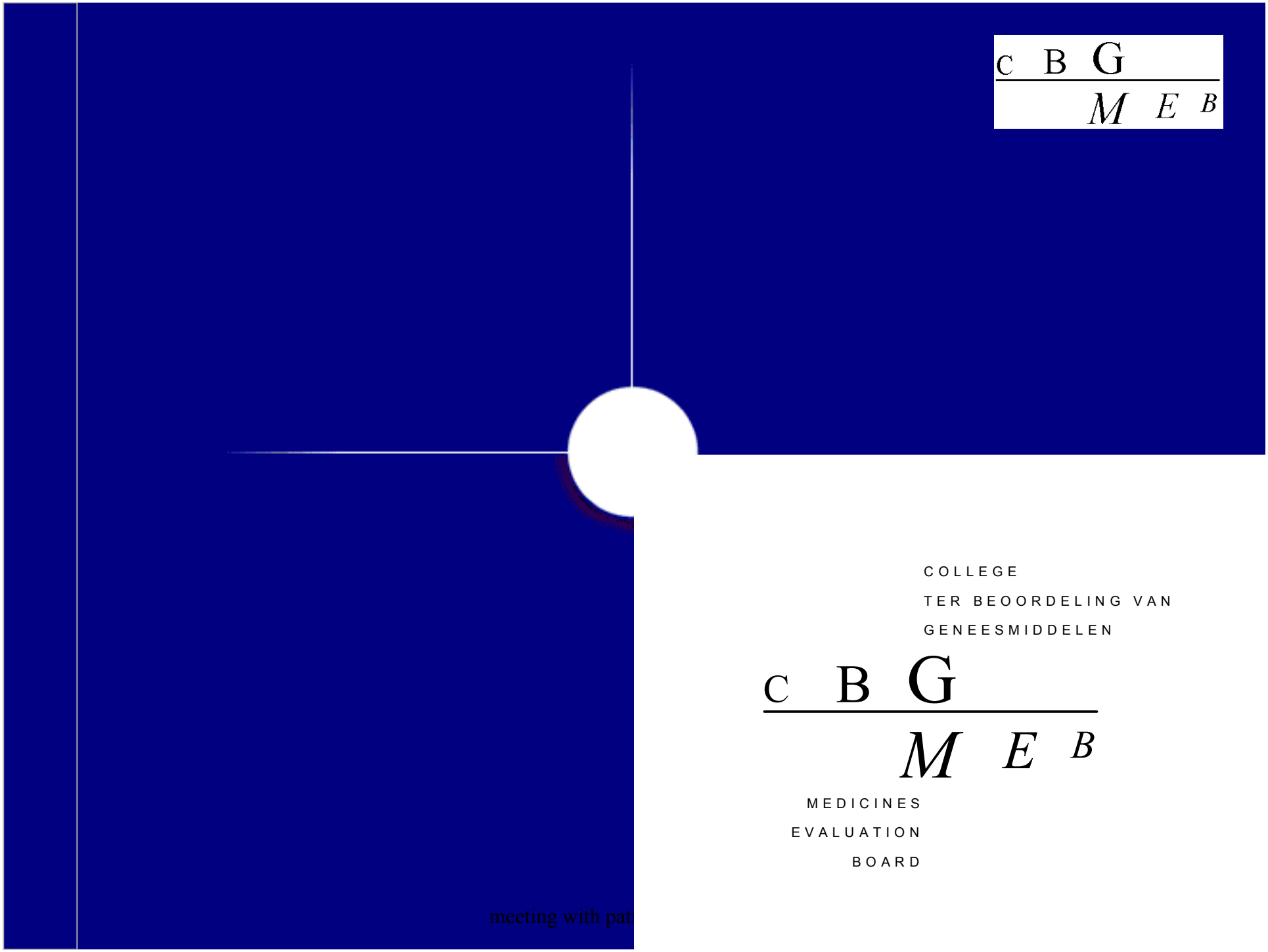
topics to work on

- pharmacovigilance
- product information
  - patient information leaflet
- dissemination of information
- transparency

title of this meeting

- the patient is waiting
- the EMEA / CPMP is waiting and listening

- I hope and expect this meeting will stimulate an active input from consumers / patients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