COLLEGE

TER BEOORDELING VAN

GENEESMIDDELEN

CBG

MEB

MEDICINES

EVALUATION

BOARD

Transparency at the MEB: a necessity

Aginus A.W. Kalis, executive director MEB

Content

- Introduction
- Basic principles
- (Dis)advantages of complete transparency
- Transparency how?

  Agenda; Minutes; PAR; PSUR (new development)
- Definition of commercially confidential information and personal data
- Need for harmonised approach
- Recommendations & summary

Introduction

- All information of the competent authority has to be publicly available (except….?)
- Physicians must have access to all documents concerning scientific evaluation of the risk-benefit balance of a medicinal product
- Patients, lawyers etc. must have access to the same information
- Need for harmonised approach between Member States/EMEA

Basic principles

- The principal right for every patient (or his representative) to know why (on the basis of what data and grounds) a medicine is prescribed to him
- The ability of physicians and pharmacists to know on the basis of what data and grounds a medicine is granted access to the market

Advantages of complete transparency

- Increase of rationale and quality of medical treatment by physicians
- No ill-founded conclusions about secretness of farmaceutical field

Disadvantages of complete transparency

- unwanted effects to competition in the pharmaceutical market place:

1. Commercial interest and innovation could be harmed??
2. Innovative firms will suppress generic applications??

- Personal data i.e. patient information could become public
- Many requests for information could harm the European system of evaluation and the daily business of EMeA and NCAs

Transparency how?

Agenda

- Active substance (moiety only)
- Type of application (market authorisation or variation)
- Type of procedure(CP, MRP, DP, or other)
- Role of MEB (NL=(co)rapp, NL=RMS, or other)
- ATC-code level 3 (e.g. ATC A10A = insulins and analogues)

Minutes

- During the discussion of the draft-minutes the MEB determines the status of publicity of the parts of the minutes
- The minutes are open for the public after a definite decision has been taken
- The minutes will be anonymised and

1. Information leading to individual persons and
2. Commercially Confidential Information

will be deleted

Public Assessment Reports

- The MEB decided to follow the principles for PARs in the mutual recognition and decentralised procedure, as laid down in the CMD(h) Best Practice Guide of January 2006
- The PAR is written in English

Trouw
Zorg
20 oktober 2008

Trouw maakt veiligheidsrapporten openbaar

SI Exif

Op deze pagina staan de vertrouwelijke veiligheidsrapporten van een aantal veel voorgeschreven geneesmiddelen, waarin de farmaceutische industrie zelf de wereldwijde meldingen van bijwerkingen vastlegt en beoordeelt. Ze heten officieel Periodic Safety Update Reports, kortweg PSURS, ze zijn Engelstalig.

In de PSURS wordt beschreven welke bijwerkingen er zijn gemeld in een beperkte periode van een jaar of korter. Fabrikanten sommen niet alleen de bijwerkingen op, maar analyseren de meldingen ook en zijn verplicht aan te geven of er gevolgen moeten worden verbonden aan het vaker voorkomen van een bijwerking.

PSURs: new development

- The MEB decided to grant access to Periodic Safety Update Reports on request
- EU Directive 2001/83/EC Art 102: information on adverse reactions shall be made permanently accessable to all MSs and without delay to the public
- PSURs may only be provided if accompanied by its assessment report of the MEB
- The assessment report of the PSUR gives an independent analysis and a conclusion on the benefit/risk profile of the product

What is commercial information and should be confidential

- Only the chemical-pharmaceutical data (module 3), because it concerns the competitiveness of a company and it concerns technical data, e.g. on synthesis of the active substance and on the manufacture
  - And in priciple it doesn't concern **Public Health** interests

Definition of personal data

- The legislation regarding the protection of personal data does not define what are personal data in the pharmaceutical field
- In general efficient anonymisation of the information would require the deletion of information on:

1. age
2. country
3. identification code

- In the end personal data means: information reducible to an identifiable natural person

Limits of transparency

- Common policy needed to define which information cannot be disclosed
- Personal data of individual persons cannot be disclosed
- Commercially confidential data cannot be disclosed
- Agencies should delete this information before documents are released.
- Before release of information provided by MAH consultation with MAH is neccesary

Need for harmonised approach

Why?

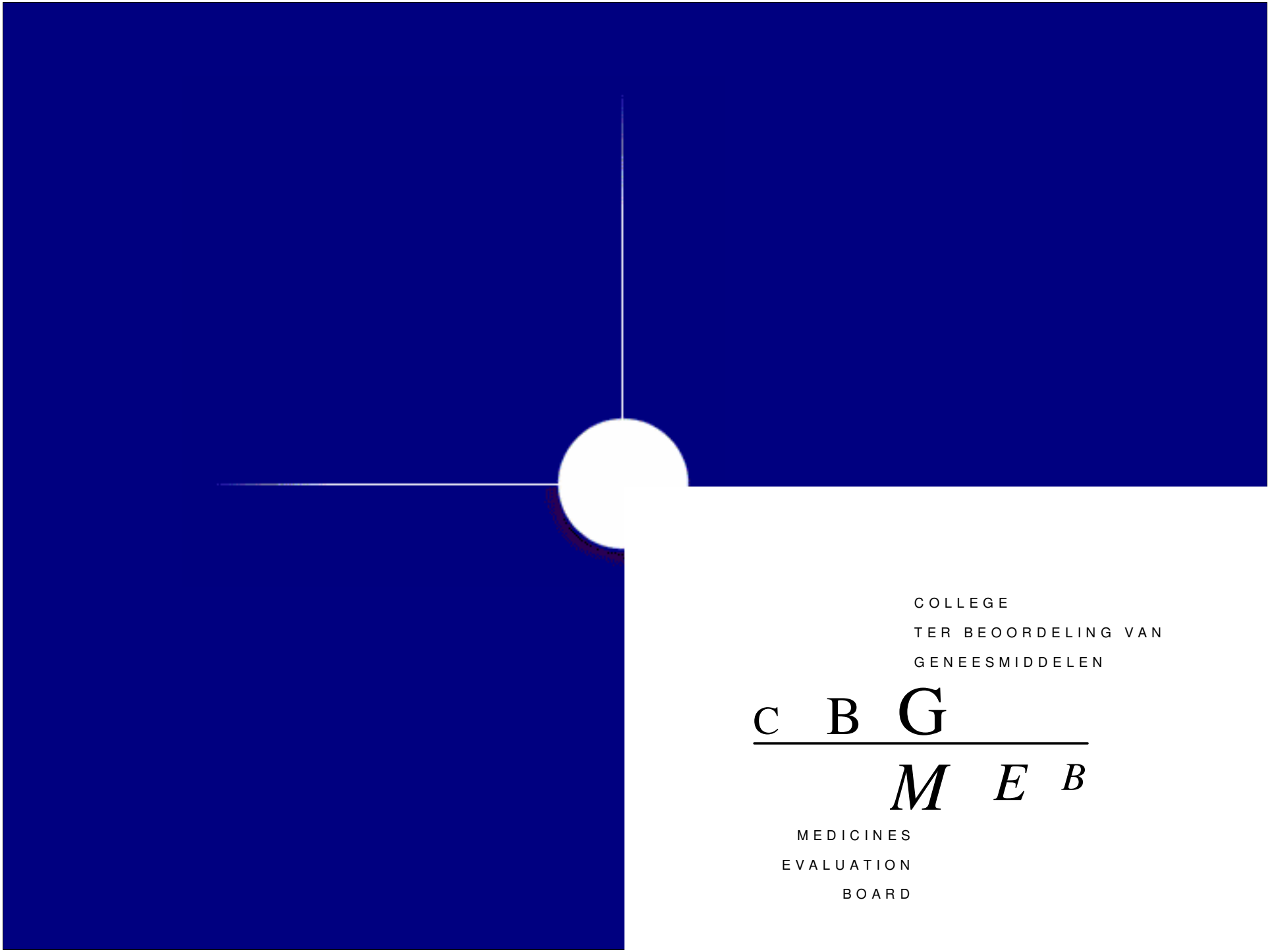
- Without general principles for active publication and for reactive disclosure the European system will be undermined
- Need for common definitions on commercial and personal information
- Need for more information to be published such as PSUR assessment reports

Recommendations on Transparency

- Disclosure of information on on-going procedures is not acceptable, because the (European) decisionmaking procedure will be undermined
- Same position for innovative products and generics
- A stepwise approach is needed; next step would be implementation on transparency of PSURs.
- Third step: maximal transparency with all kinds of other documents

Summary/Discussion

- We have to rapidly move forward on transparency
- Do you agree on the proposal for common definitions on commercial and patient confidential information?
- We need an European harmonised approach for a sound medicinal evaluation system



COLLEGE
TER BEOORDELING VAN
GENEESMIDDELEN

CBG
MEB

MEDICINES
EVALUATION
BOARD