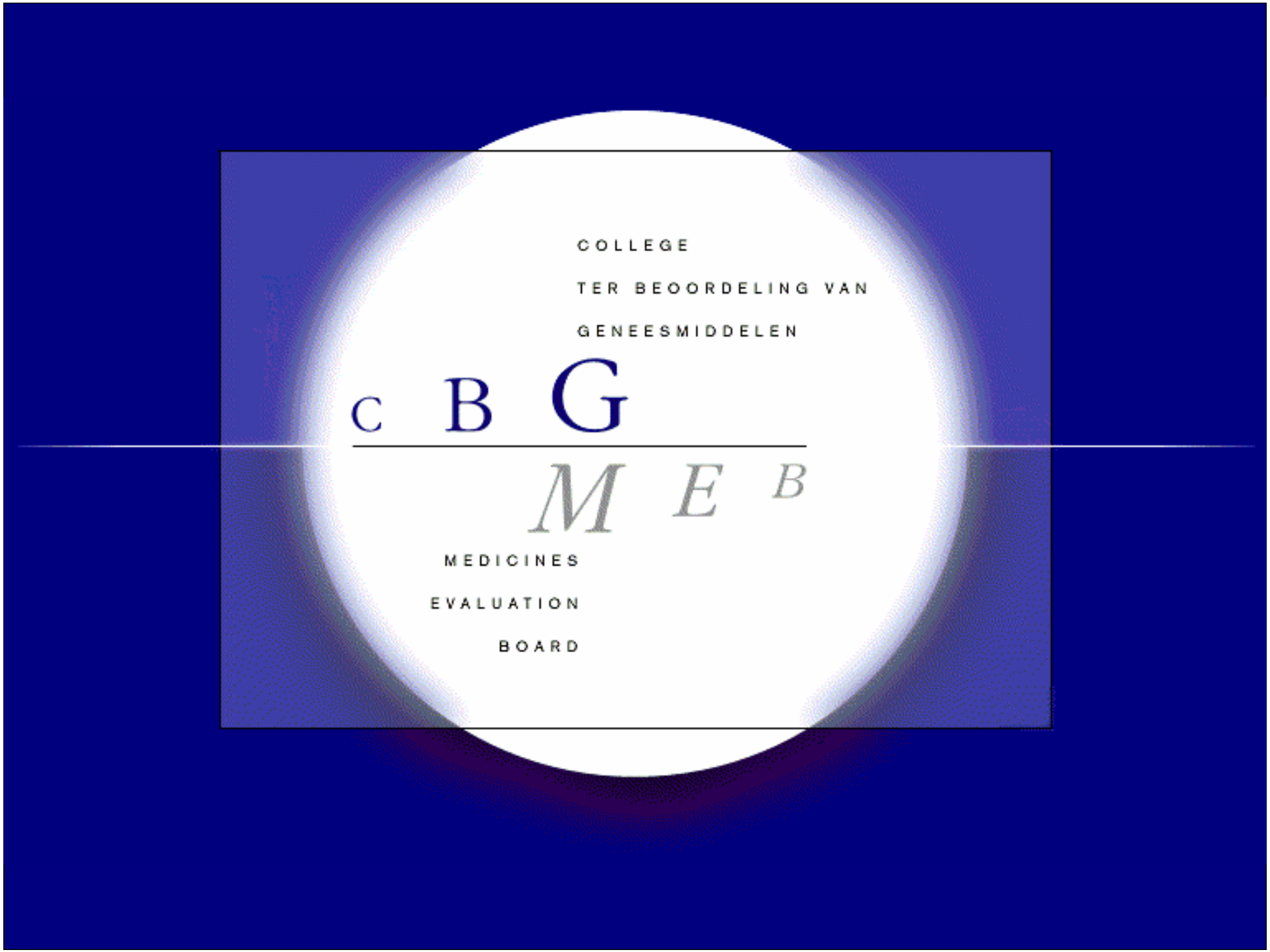
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CBG – MEB: National and European developments

Aginus A.W. Kalis

Topics

- Introduction
- The choices of a national Competent Authority anno 2006
- Developments in Europe
- Developments in the Netherlands
- Conclusion

Introduction

- **MEB in the middle of changes**
  (I apologize for being egocentric)
- **European legislation just renewed**
- **New Dutch legislation will be implemented**
- **European network of regulatory agencies in evolution**

The choices of a National Competent Authority anno 2006

- **Review 2001 and EMeA Road Map to 2010: EU network of National and European Competent Authorities**
- **Every Member State chooses his level of responsibility, with respect to:**
  - **Functioning as rapporteur in CP**
  - **Acting as RMS in DCP and MRP**
  - **Taking the lead in European discussions**

Developments in Europe

- **Further Improvement of the procedures:**
  - **Faster access to innovative medicinal products**
  - **Better knowledge / science base for authorised medicinal products**
  - **Harmonization**
- **Strengthening of pharmacovigilance:**
  - **Risk Management Plans**
  - **Work sharing**
  - **Better knowledge science based**
  - **ICT: Electronic Medication Dossier**

Developments in Europe (2)

- **From GxP for pharmaceutical industry to Good Regulatory Practices in competent authorities:**
  - **Development of Quality thinking**
  - **European Benchmark**
- **Strengthening of transparency**
  - **Accountability**
  - **Make better use of existing knowledge about medicinal products**
  - **"New" stake holders: patients and health care professionals**

Developments in the Netherlands

- **2004 - 2005: business plan developed**
- **Main objective defined:**
  - **Maintain position in Top 5 of Europe:**
    - **Choice of special-interest areas**
    - **Maintain quality of work**
    - **Strengthening of Pharmacovigilance**
    - **ISO-certification**
    - **Establish a transparent organisation**

Developments in the Netherlands (2)

- 2005: Pharmacovigilance department re-established.
- 2005: Veterinary Department
- 2005: Novel Foods Unit
- 2006: Covenants with academia and university hospitals
  - Topics: special interest areas, pharmaco-epidemiology
- 2006: ISO 9001:2000, quality assurance system

Developments in the Netherlands (3)

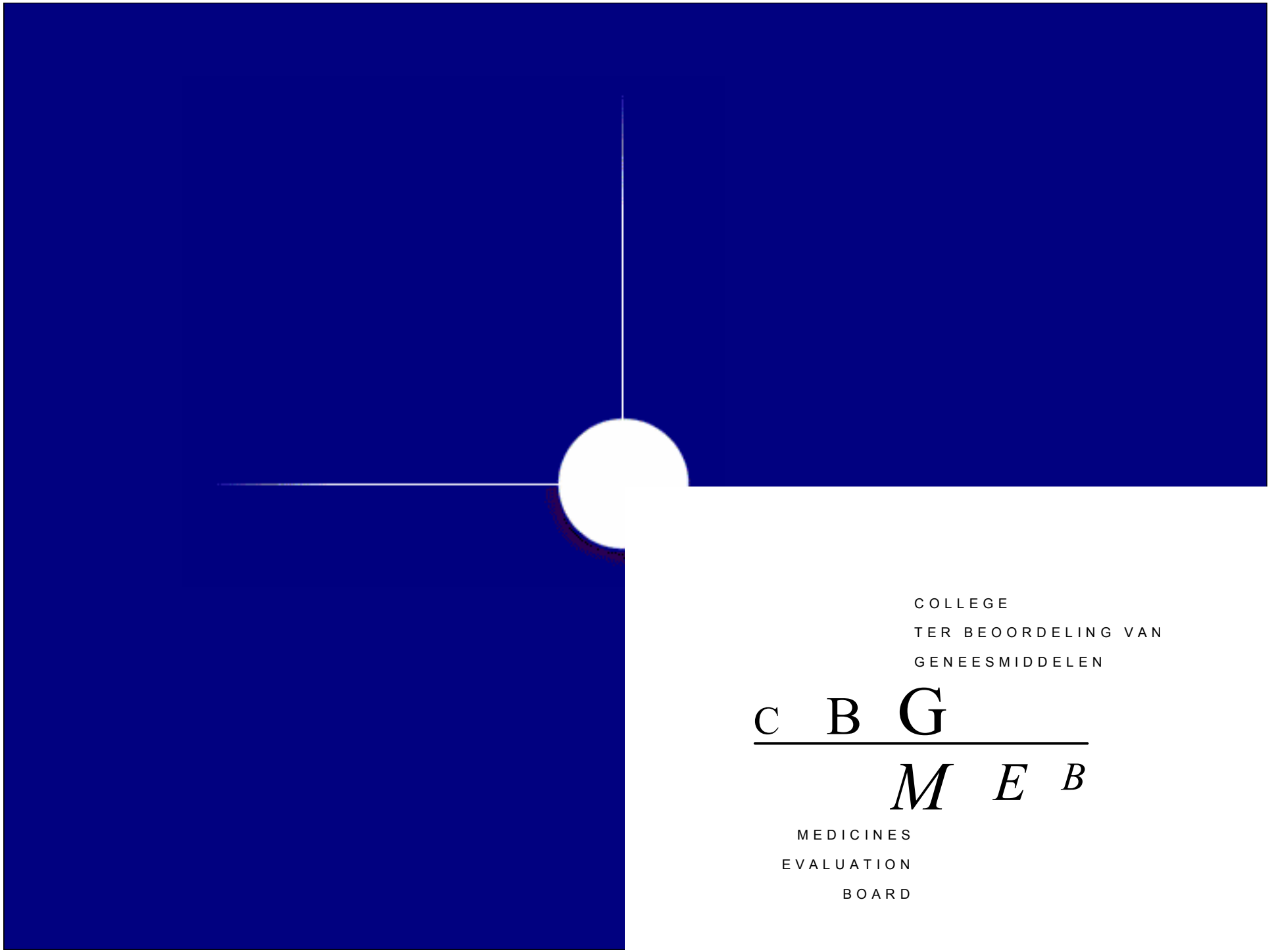
- **Future (2007): Organizational changes:**
  - **New IT system ICI**
  - **Paperless environment, electronic submissions**
  - **Workflow Management**
  - **Moving to a new office building**

- **Strengthening national collaboration between competent authorities**

Conclusions

- **Networking organisation**
- **Challenging times**
- **Ongoing reorganization**
- **Ongoing improvement**

For a golden future of the European Regulatory System and for Public Health!



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