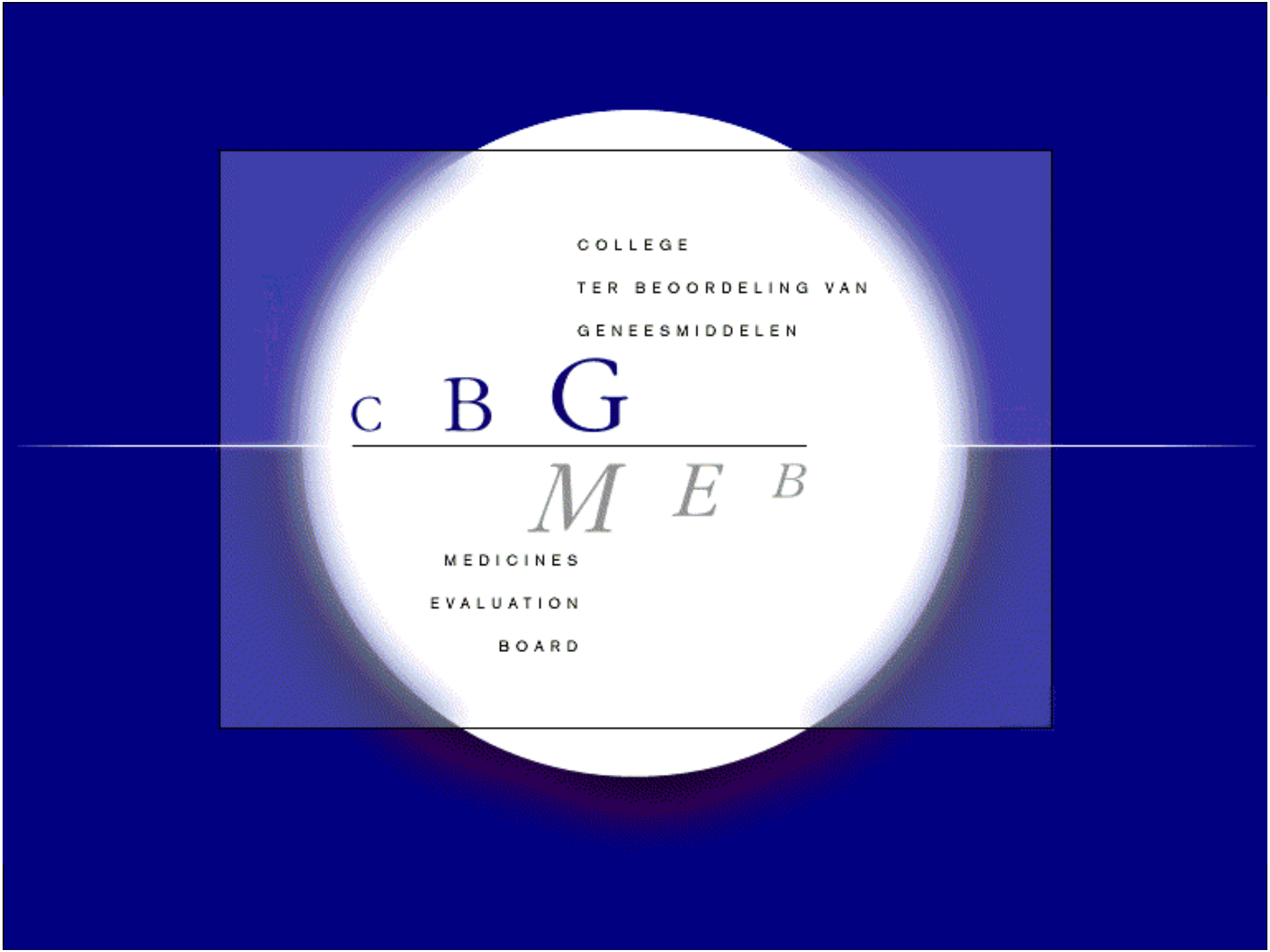
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View of a Member State on the Decentralised Procedure

Dr. W.F. van der Giesen
Medicines Evaluation Board
The Netherlands

Content of presentation

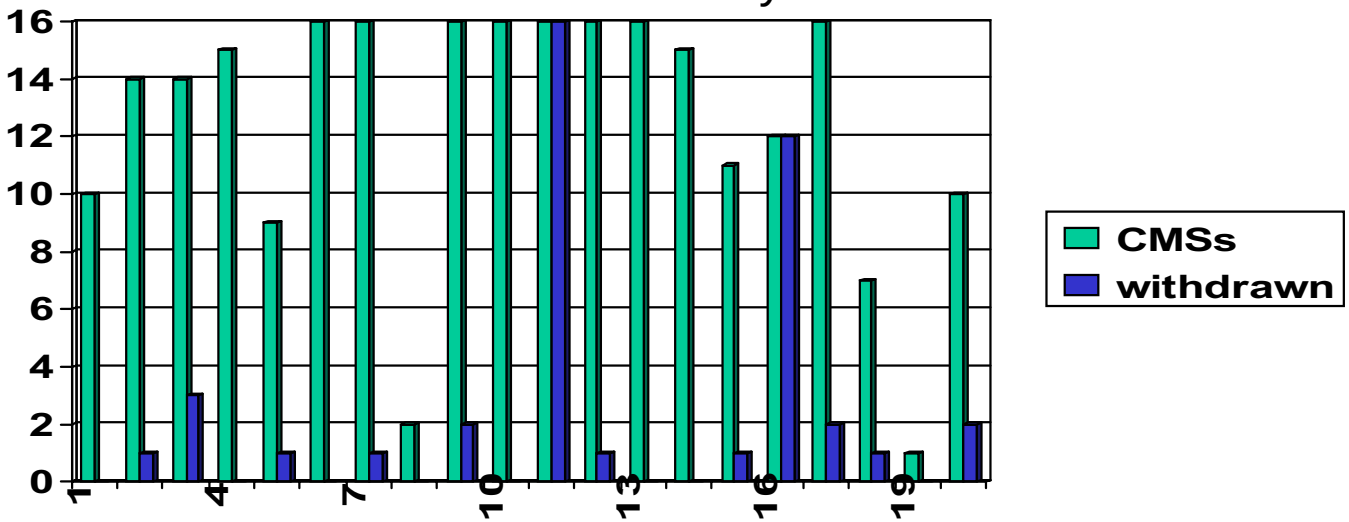
- Scope of Mutual Recognition Procedure (MRP) and Centralised Procedure(CP);
- Problems in MRP and possible solutions;
- Status of the Mutual Recognition Facilitation Group (MRFG).

Scope of CP and MRP

- The Commission considers to make the CP obligatory for all products containing a new active substance (NAS).
- Only a small minority of MSs support this idea;
- Industry would like to maintain the option for the two procedures for NASs;
- No managerial reason for the change as suggested, on the contrary …...

Scope of the Decentralised Procedure

- 20 new active substances in the year 2000



The diagram shows that:

- The number MRPs for NASs is comparable to the number of CPs for part B products;
- Divided views in MRP for NASs is comparable to divided views in CPs;
- MRP is not a failure for NASs;
- No need to make the CP obligatory for NASs.

Negative effects of changing scope CP and MRP

- All NASs in the CP could easily overload the system;
- Some national agencies may not survive (not possible to maintain critical mass), whereas the CP is heavily dependent on the national agencies.

Other products than NASs

- Two other large groups:
  - Line extensions: usually without creating problems in MRP.
  - Generics: usually creating problems in MRP

Line extensions

- Companies are allowed to use national procedures for line extensions of authorised medicinal products without harmonised SPCs (NtA, Chapter 1, section 3.3)
- Consequence: companies use the MRP only for line extensions of products for which an (almost) harmonised situation exist.

Generics

- All MSs prefer to authorise generics under the same conditions as the corresponding innovator product.
- Most MSs accept minor deviations in SPCs of generics in MRP as compared to the SPCs of innovator products.
- The real issue is the not-harmonised situation for innovator products in the MSs.

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How to improve the MRP for generics?

- A new application procedure along the lines for Type II variations will not improve the situation because the innovator product is not the subject of the procedure.
- Harmonising the innovator SPCs via an Article 11 procedure is a heavy instrument, very demanding for all parties.
- New creative legislation is needed!

Harmonisation of SPCs of innovator products

- A harmonisation procedure along the lines for Type II variations would be very helpful (to be initiated either by the innovator or by a MS). Only in case that no consensus can be reached the matter should be referred to the CPMP for arbitration.

Mistrust among the Member States

- Does it exist?
- CMSs have 90 days to check whether they can accept the RMS decision; it is in fact a legal duty to perform such a check.
- Some MSs say why require less information in MRP than in national procedures?
- Current practice in MRP does not work corrective.

How to improve the MRP in general?

- We have already the Mutual Recognition Facilitation Group (MRFG), however this group has no formal status, deals with procedural aspects only. The so-called break-out sessions have no binding character. MSs are not bound to the outcome of break-outs.
- It would be a major improvement to give the MRFG a formal status, e.g. of an advisory committee to the MSs

The MRFG as formal advisory committee

- One member per Member State;
- Chairman to be elected for three years;
- All MRP applications are to be dealt with;
- Decisions to be taken by majority in a transparent way;
- Decision is an advice to CMSs.

Referral to CPMP for arbitration

- If a CMS can not accept the advice given by the MRFG the matter is referred to the CPMP for arbitration.

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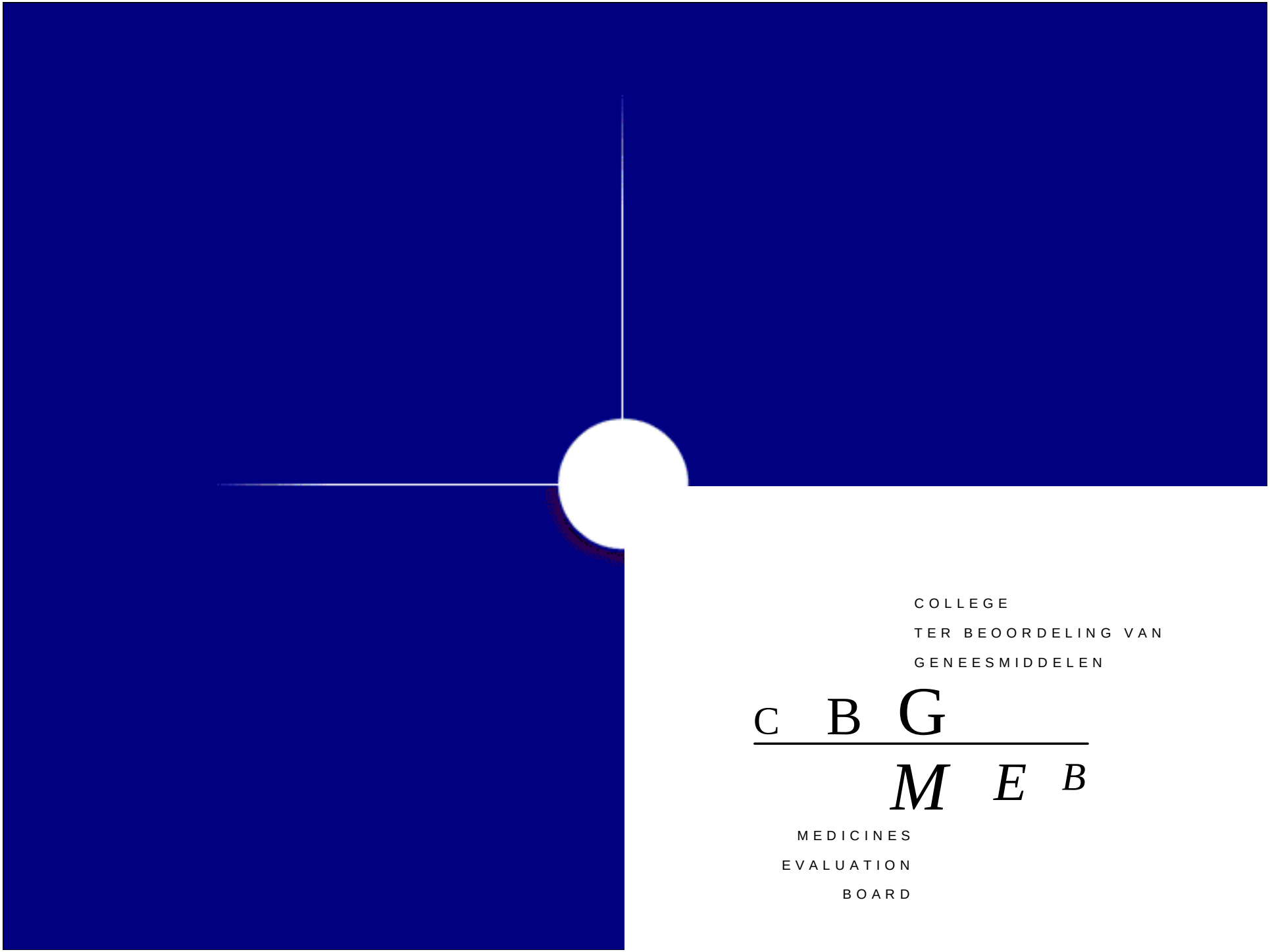
Other points

- Generics of CP products also in MRP;
- Article 11 and 12 should not by definition comprise the whole dossier including the SPC;
- Implementation of Commission decisions in Article 10, 11 and 12 is a task for the MSs and should not be changed.

Main Conclusions

- MRP as option for NASs should be maintained;
- The MRFG should have a formal status, e.g. as advisory committee to the MSs;
- There is a need for workable legal instruments and procedures to harmonise SPCs of innovator products.



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