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TER BEOORDELING VAN

GENEESMIDDELEN

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# ***Registration of heroin as a pharmaceutical product***

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## **Recommendation of the CCBH to the minister of health:**

In order to create prescription facilities to physicians operating in special heroin treatment units and to secure regular safety monitoring of this medicine, a registration of both heroin base and heroin HCl should be obtained.

## Registration

- Why?
- How?
- What?

## Why registration of medicines

- Use and misuse of medicinal products since the beginning of history
- Responsibility was on doctors and pharmacists
- In 1799 first suggestion to establish a registration authority

## The Medical Physical Journal, 1799:

“....we should submit to the legislature the propriety of erecting a public board composed of eminent physicians for the examination, analysis and approbation of every medicine before an advertisement should be permitted into any newspaper or other periodical publication and before it should be vended in any manner whatsoever.”

## **Impetus for modern legislation came from:**

- Safety concerns (thalidomide)
  - Change from medical art to medical science
- => public health is a responsibility of the Government

## **Is registration still necessary in a time of moving responsibilities?**

- Wish of individual patient becomes more important
- Treatment contract between physician and patient, including informed consent
- Industry liable for damage

## Registration is still necessary as

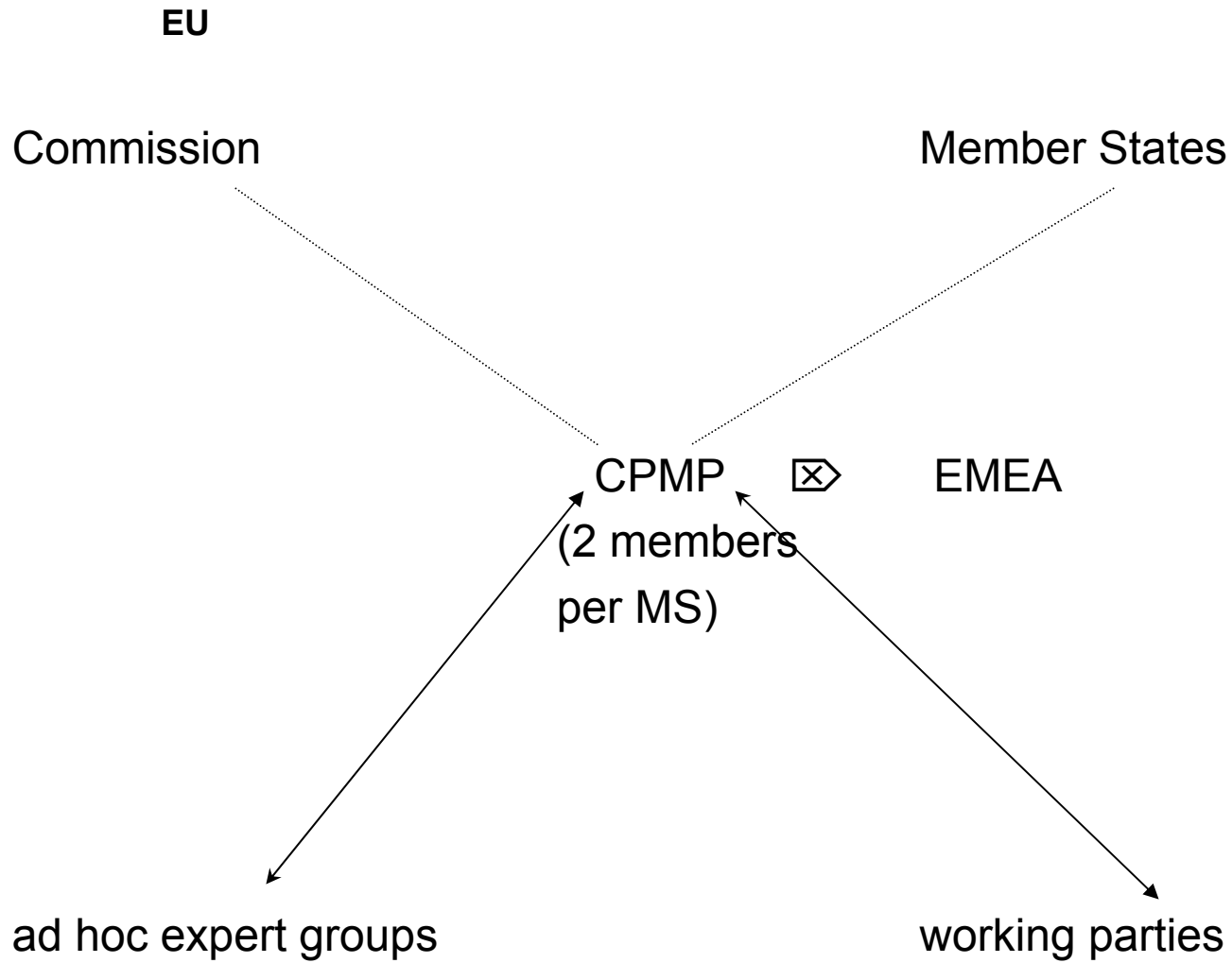
Need to ensure:

- high pharmaceutical quality of a medicinal product
- adequate demonstration of efficacy and safety
- well developed pharmacovigilance

## Registration: how is it done

- In EU:           centralised procedure  
                  decentralised procedure

National in one Member State



## Centralised procedure

- Application made to CPMP/EMEA
- Rapporteur and co-rapporteur chosen from CPMP members
- Assessments discussed in CPMP => opinion
- *Commission agrees with the opinion => decision binding for the whole EU*

## Centralised procedure

- Obligatory for all biotech products
- Option for new chemical entities

## Decentralised procedure/ mutual recognition

- Application made to one national authority (RMS)
- Assessed by this authority.
- When approved the company can ask licence in one or more Member States, based on the first approval .
- Reason to refuse a license by Concerned Member State (CMS) based on major health risk  
↓ withdrawal in one or more Member States or Arbitration in CPMP

## Decentralised procedure

- Option for new chemical entities
- Mandatory route for generics

# Registration in the Netherlands <sup>C B G</sup><sub>M E B</sub>

registration

Second round?



## Option for typical national products

If the company considers export, a decentralised procedure should be started.

## What data are necessary pre-licensing

- Pharmaceutical quality
- Non-clinical pharmacology  
Toxicology
- Human pharmacokinetic data  
clinical efficacy and safety data

=> Summary of Product Characteristics (SPC)

## What data are needed post-licensing

- Maintenance of pharmaceutical quality
- Follow-up of human safety through pharmacovigilance (PSUR's)
- New clinical data if a change in the SPC is indicated or asked for

## Examples:

- Methadone: via mutual recognition
- Buprenorphine: national (not in all MS)
- Orlaam: central (revoked)
- Nicotine Replacement Therapy: national and via mutual recognition
- Zyban (bupropion): via mutual recognition
- Campral (acamprosaat): national

## Conclusion

Registration is needed for heroin:

- As it is indicated for medical prescription
- To ensure pharmaceutical quality
- To follow safety of the product by pharmacovigilance



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