Umsetzung des Review 2004

Auswirkungen auf das Europäische Zulassungssystem

insbesondere auf das dezentrale und das MR-Verfahren

DGRA - Jahreskongress

9. Juni 2005, Bonn

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Bundesministerium für Gesundheit und Frauen

Wien

Two options for granting a MA for MP´s – not falling under the scope of CP

- MRP
  - Altered („forced arbitration“)
  - For products with an existing MA
- DCP
  - Alternative review procedure
  - Only possible, if no authorisation has already been granted

Both procedures possible for all kind of products (except those which are mandatory for CP), but different starting points

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Pre-submission meeting

On a volunteerly basis – for MRP & DCP

- Applicant discussions with RMS, in order to clarify regulatory issues (e.g. legal basis) and principle questions concerning availability of experts (TT)
- About 6 to 4 months in advance of the start of the procedure

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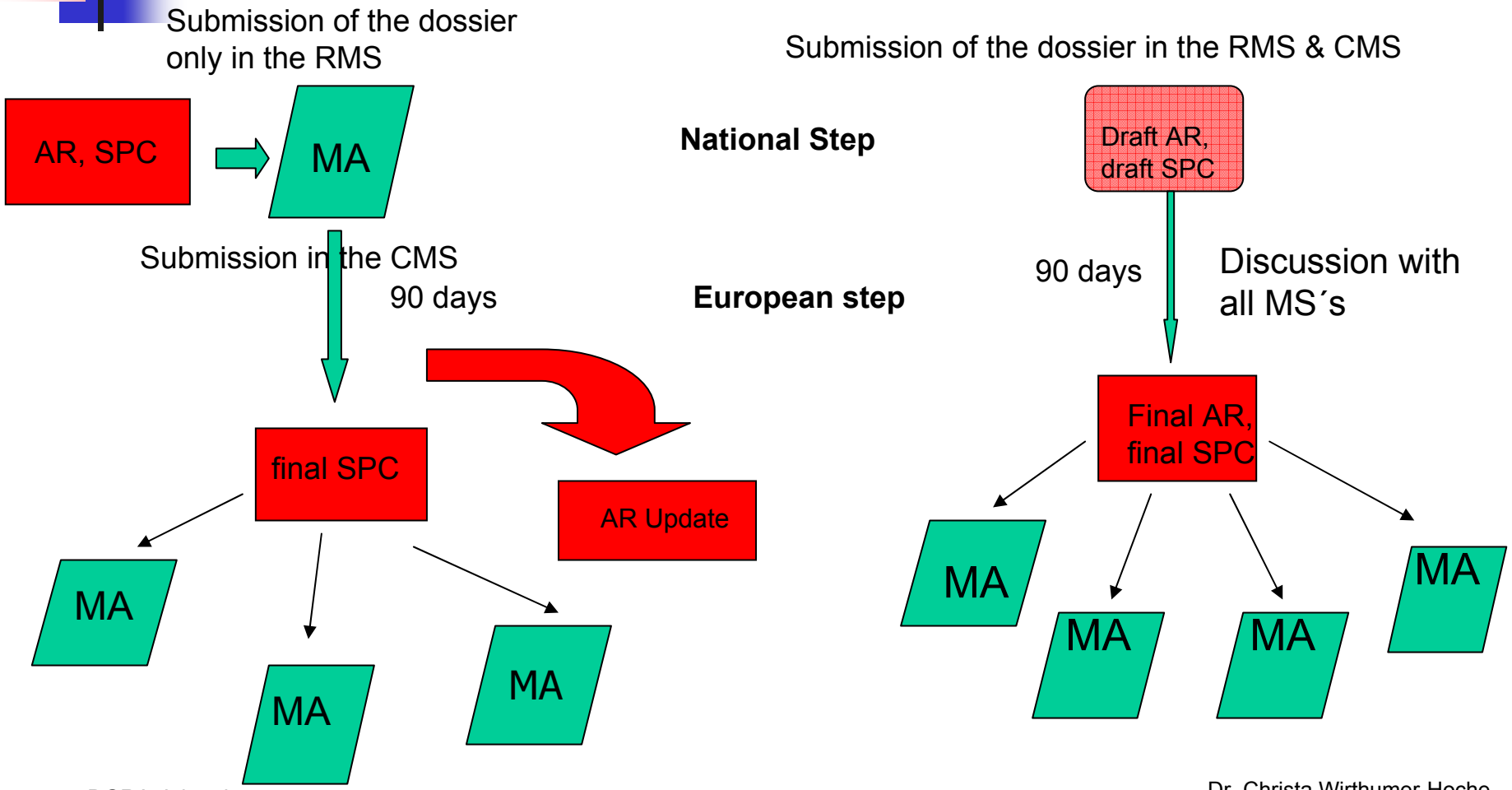
MRP vs. New Decentralised Procedure



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DCP - proposed flow chart

In order to follow the time-lines of the Directive, the following steps are proposed:

Pre-procedural step	for validation
National step	120 days for RMS to prepare the draft AR, draft SPC,…
Clock-stop	Q – responses
European step	90 days to find agreement

Assessment process: 210 days except clock-stop

Agreement:

National step	30 days for granting MA

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New Decentralised Procedure

New element of the procedure:

*Consultation between MS´s **before** the first marketing authorisation is issued.*

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DCP, MRP

European step – Art. 28(5) Dir 2004/27

"Each MS in which the application has been submitted in accordance with paragraph 1 shall adopt a decision in conformity with the approved **AR, the SPC and the labelling and package leaflet** as approved, within 30 days after acknowledgement of the agreement.

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Package leaflet – harmonisation – new issue

Is a harmonised view achievable?

- Prescription status is not part of the harmonisation (Rx vs. OTC) – still a national issue
- Is the same PL acceptable or has it to be identical?
  - Harmonisation on content and order must be achieved, but
  - PL wording – at least in the introduction for Rx- or OTC-products – is different
  - Special national requirements in certain sections of the PL
    - "Blue Box"- requirements in the PL per MS – update of the readability guideline

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Package leaflet – harmonisation

- Standard templates for SPC, PL & label
  - Use the same in MRP & DCP as for CP
    - QRD-templates
      - ➢ Harmonised format, order and layout for SPC, PL, labelling
      - ➢ Set out standardised headings
      - ➢ Available in all official EU languages
        - ✓ At the EMEA Homepage
    - Standardisation is important – also in respect to the e-submissions (PIM-project)

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Improving the PL

- Readability test
  - Art. 63 b (2) “The PL must be written and designed to be clear and understandable, enabling the users to act appropriately, when necessary with the help of health professionals.”

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Package leaflet

Art. 59 (3) – Readability test

- ✓ „The PL shall reflect the results of consultations with target patient groups to ensure that it is legible, clear to use“
  - Necessity to perform the test in each MS-language?
  - Is one language (eg. English) enough, 3 languages?
  - Is it necessary for all kind of products?
    - Also for products which are for hospital use only?
    - Generic products, …..?
  - Timing of the testing?
    - Before the submission – test is part of the original application? Most likely the PL will change a lot during the assessment.
    - Later in the procedure?

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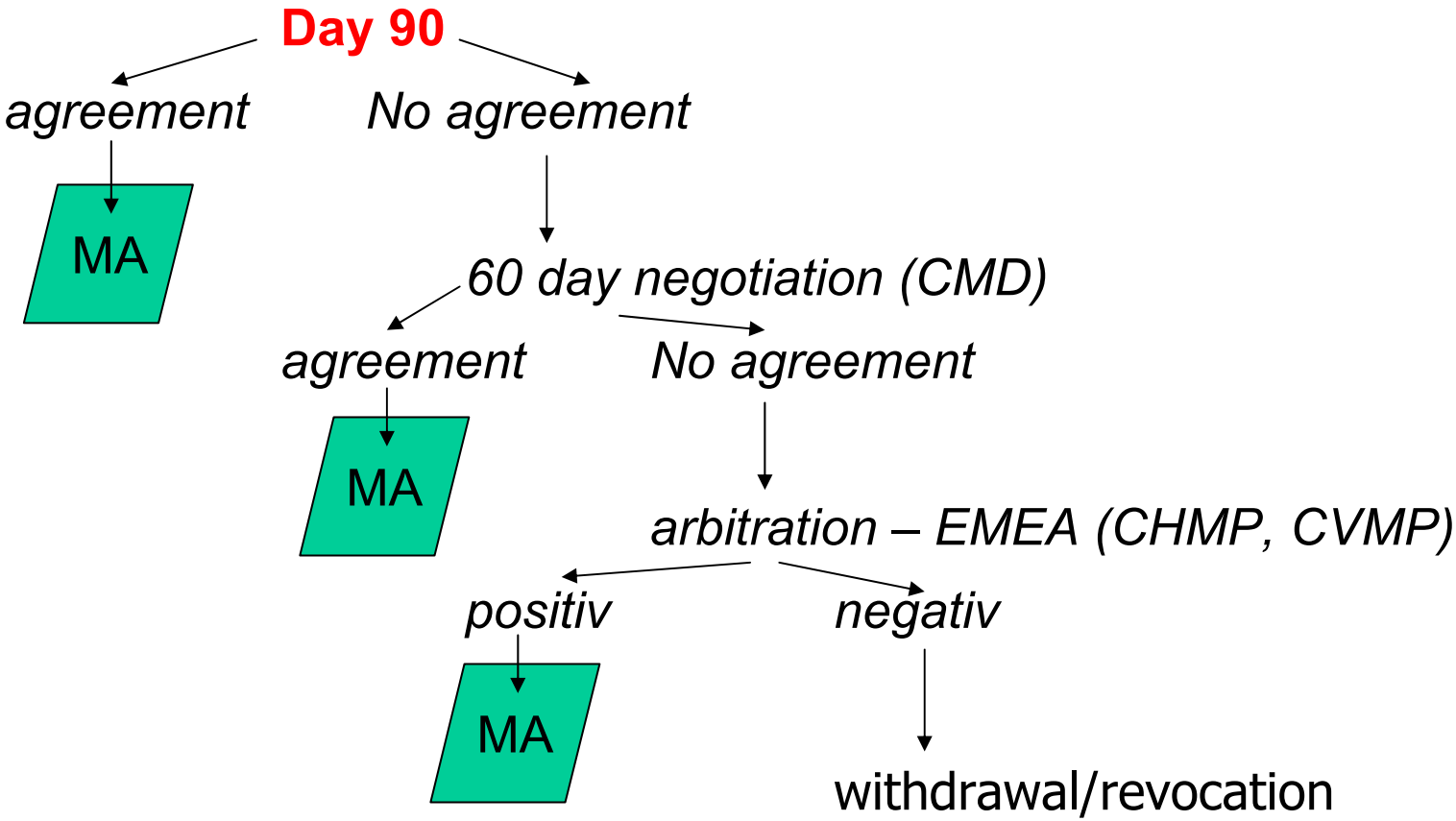
MRP & DCP – situation after day 90



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MRP, DCP

A CMS cannot agree with the AR & SPC, PL, labelling, and is raising serious potential risk to public health (Guideline published)

➡ The elements of disagreement shall be forwarded to the CMD (former MRFG)

- Within the CMD the MS´s shall use their best endeavours to reach agreement
  - Possibility for an oral explanation of the applicant

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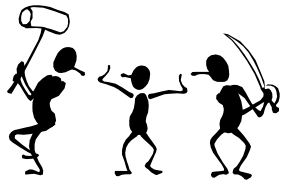
MRP & DCP

If no agreement can be reached

- Still disagreement after this consultation – the elements of disagreement „serious public health concerns“ are forwarded to the Agency

→ „forced“ arbitration



→ MS´s that are in agreement with the AR & SPC, PL & labelling may authorise the medicinal product, without waiting for the outcome of the procedure

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MRP / DCP

- Preparing for a MRP/DCP
  - Choice of the RMS
  - Choice MRP/DCP?
  - Choice of the CMS – all or selected (stepwise entrance into the EU)
  - Time during the calender year
  - Availability of RMS experts/company experts during the procedure?
  - Contacts and relations with the RMS (CMS) before/during the procedure

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MRFG → Co-Ordination Group for MRP & DCP (CMD)

- ***Dir. 2004/27 Art. 27***
  - With a legal status
  - One representative from each MS, appointed for 3 years (renewable)
  - Members could be accompanied by experts
- Dialogue between MS´s
- Monthly meetings at the EMEA, EMEA provides secretariat
- Rules of procedure - currently discussed at the MRFG
- Operational - Nov. 2005
  (Start – old MRFG with CG-members – April 2005)

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Co-Ordination Group

- Dialogue between MS´s
  - Procedural / regulatory
    - Regulatory SOP´s, guidelines and recommendations
    - Harmonised view on the interpretation of Dir & Reg
  - Scientific
    - Scientific discussion to resolve scientific problems, arbitration only in exceptional cases
    - Identification of the need to modify or develop new guidelines (establishment of ad-hoc groups)

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Co-Ordination Group

- Harmonisation of SPC´s
  - Once a year the CG will elaborate a list of products where the SPC need to be harmonised
- Risk management
  - Close liaison with the Pharmacovigilance WP
  - Arrangements for work sharing of PSUR´s

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Thank you !