BfArM
Federal Institute for Drugs and Medical Devices

# Reinforcing patient safety in Europe

## Accession preparation II

## Preparing for dossiers evaluation

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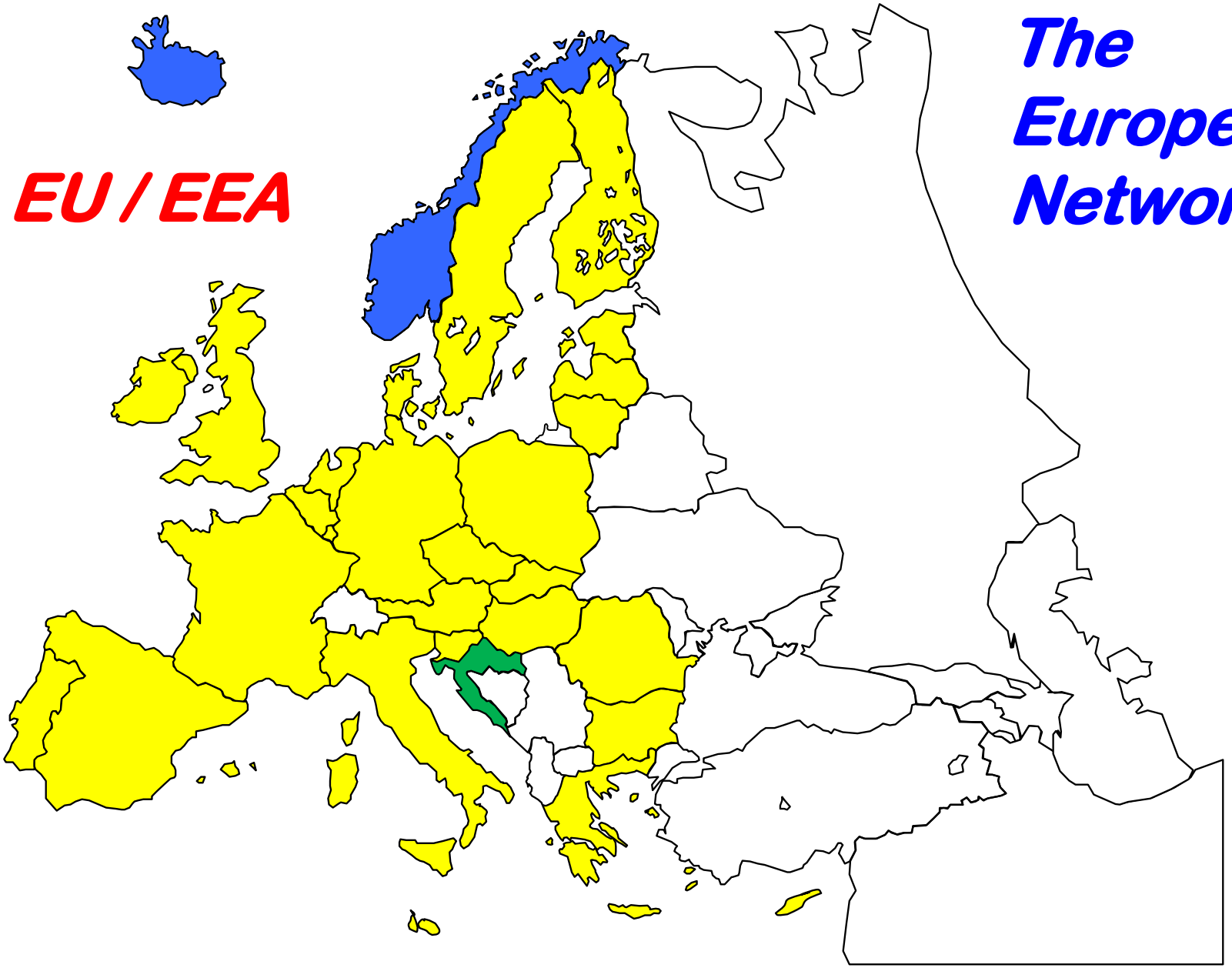
# The European Network



# The European Network – (1)

- consists of
  - National Agencies
  - EMA
- is about best use of available resources
  - limited
  - not equal distributed in the EU
- is based on Worksharing
  - European procedures (CP, MRP, DCP)
  - started 1995, but still a youngster

# The European Network – (2)

- is based on two pillars
  - Rules
    - Legislation
    - Guidelines, Best Practice, SOP‘s, …
  - Trust
    - the human aspect
    - has to evolve and takes time

# … European Pharmaceutical Legislation

- Directive 2001/83/EC, as amended (human)
- Directive 2001/82/EC, as amended (veterinary)

to be transposed into national legislation

therefore

- harmonised data requirements and assessment for a marketing authorisation are in force in the EU/EEA

but

- prescription status (Rx / OTC)
- reimbursement by health insurance funds

are within the competence of the national states

# … basic principles

- no approval „light“ for known active substances, but the same basic principles are applicable as for a medicinal product with a new active substance.
- each application for a marketing authorisation is assessed in line with the principles of
  - ✓ efficacy
  - ✓ safety
  - ✓ quality

  and approved if the benefit-risk-ratio is positive
- but the amount of data within the application for a marketing authorisation may differ

# … data requirements

- for new active substances we count on scientific data and evidence
- for known active substances we believe in scientific knowledge and pharmacovigilance

currently the most challenging item is: to be RMS in a MRP for a ‚Well-established Use‘ application

Plea to Industry

- good quality dossier
- avoid ‘innovative’, but historical ideas

# The Regulatory Framework – (1)

- Submission
  - electronic – which format: eCTD – NeeS
- Validation
  - try to avoid national requirements, either from
    - parallel legislation (e.g. environment)
    - administrative legislation (e.g. signatures)
  - reliable internal procedures
- Accession specialities !
    - ongoing national MA applications and Article 17(2) and 18 of Directive 2001/83/EC

## Article 17(2) of Directive 2001/83/EC

*2. Where a Member State notes that another marketing authorisation application for the **same medicinal product** is being examined in another Member State, the Member State concerned shall decline to assess the application and shall advise the applicant that Articles 27 to 39 apply."*

## Article 18 of Directive 2001/83/EC

*"Where a Member State is informed in accordance with Article 8(3)(1) that another Member State has authorised **a medicinal product** which is the subject of a marketing authorisation application in the Member State concerned, it shall reject the application unless it was submitted in compliance with Articles 27 to 39."*

# The Regulatory Framework –(2)

- Accession specialities !
  - data exclusivity for reference medicinal products
    – which is counting from the day of accession and Aquis fulfillment
      - *Questions and Answers on MRP & DCP after the EU Enlargement on 1 May 2004 & 1 January 2007 (http://www.hma.eu/118.html)*
      - *Phasing-in EU-procedures: MRP and referrals Sept 2003 (http://www.hma.eu/118.html)*
  - be transparent …
- Assessment
  - you have to stick to the timelines ….

# Assessment of applications

... if you are

- CMS

  **risk based approach**

  - complete mutual trust of the RMS AR
  - mutual trust in part(s) of the RMS AR
  - assessment is based on RMS AR
  - dossier only in justified cases (DE: following consultation with Head of Unit/Department)

- RMS (or pure national)
  - you have to write the AR

# Assessment report

… is the basis for the benefit-risk decision

- national
- for CMS

- specific and continuous training needed for assessors
- how to write an european assessment report
  - to know the form and rules
  - to know the guidelines
  - to know where, who and whom to ask

# How to create Mutual Trust ?

to know the Guidelines, BPG, SOP, …

- to understand the idea behind
- common interpretation

How to be sure?

- Meetings
- Discussions
- Training (e.g. Twining, EMA, HMA, …)
- be an observer before accession

→ You will have to travel !

# Resources

… are limited by definition

With the accession

- shift from a pure national view to a mixture of european and national tasks
  - ratio?
  - speed?

  to be defined by each candidate !

Derogation list?

a problem, as you are squeezed between the old priorities and demanding new tasks

# … to be RMS

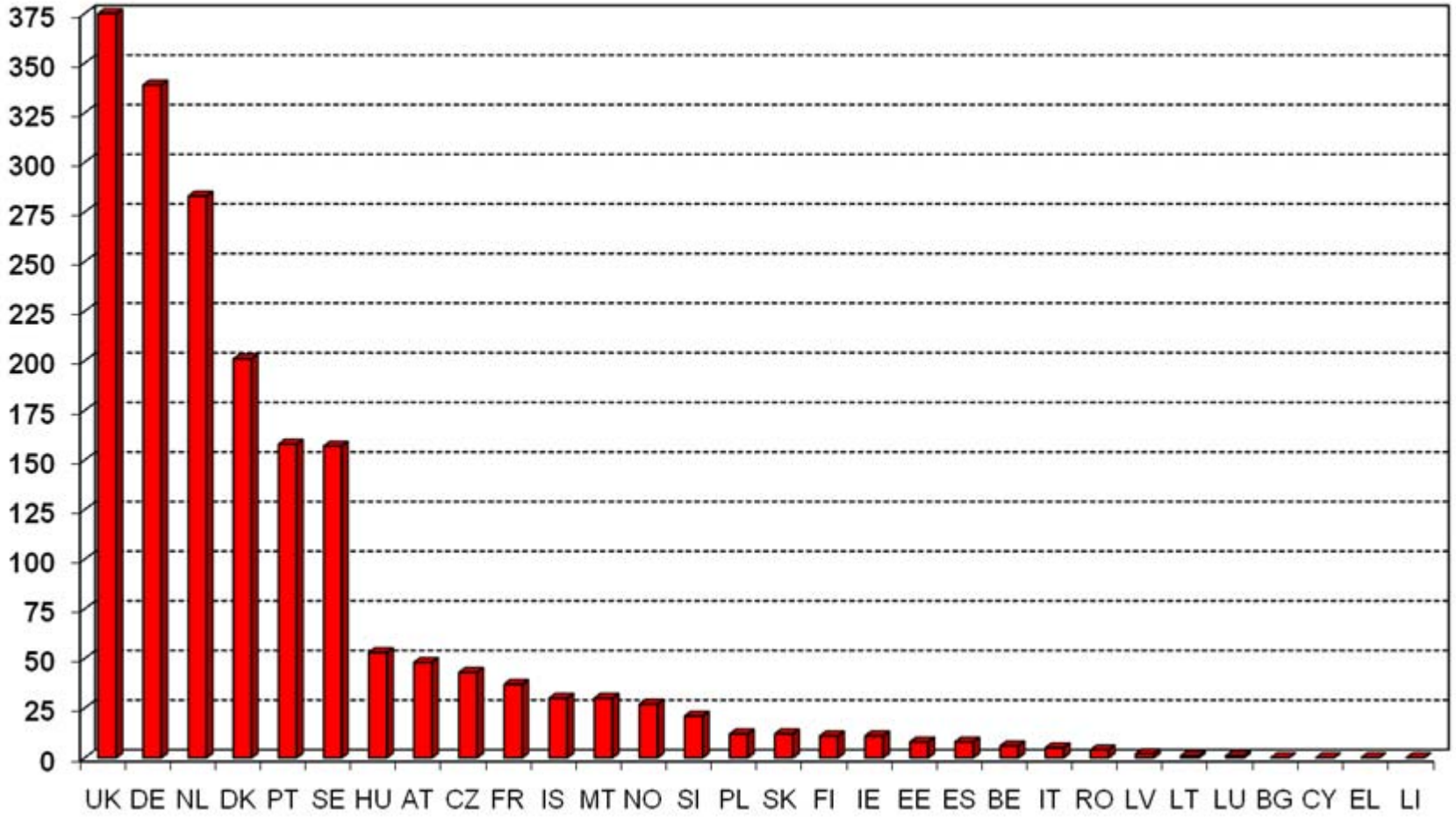
You will get demands from two sides

- the ‚insider' (national companies) looking for new opportunities in the EU
- the ‚outsider' looking for new DCP-slots

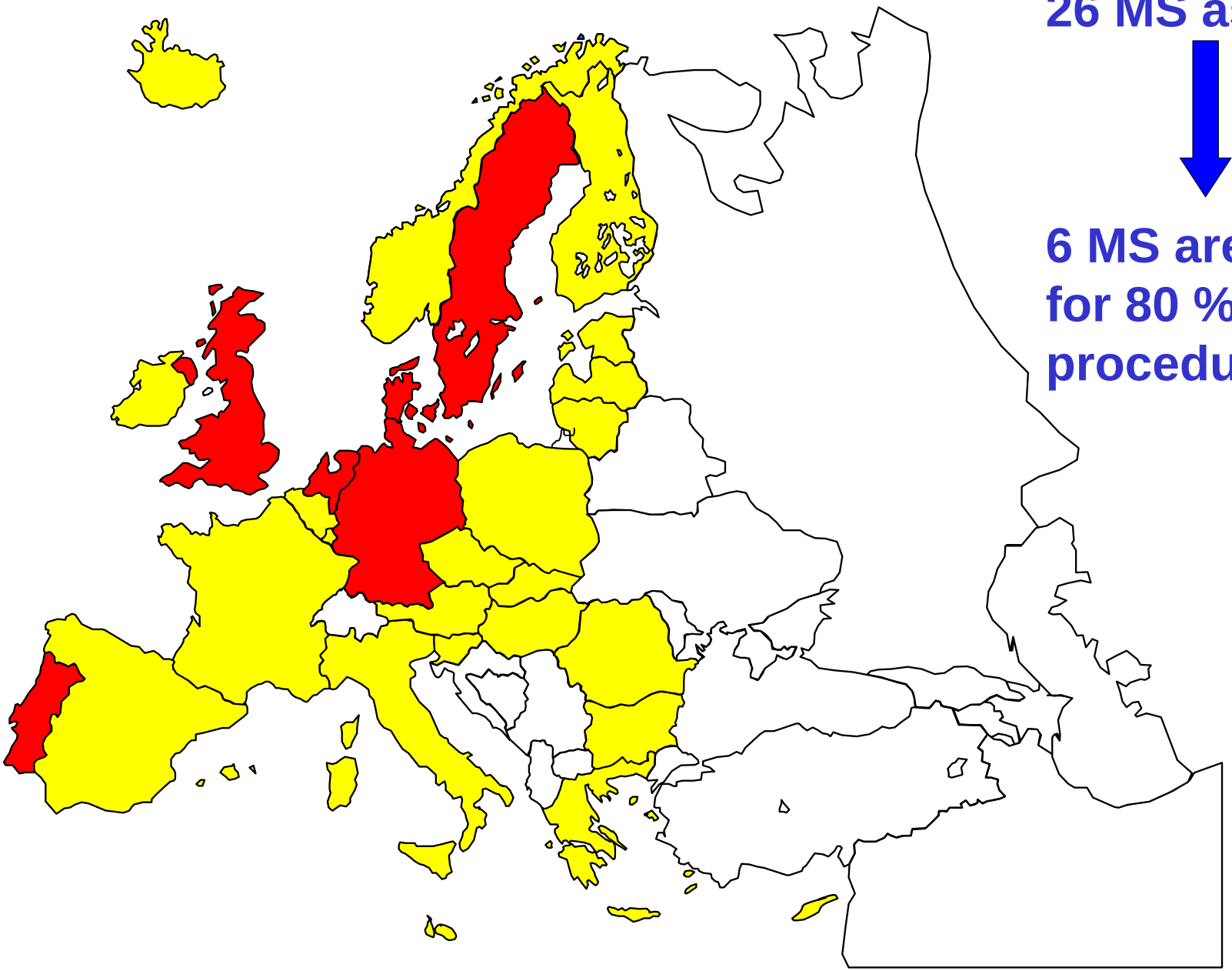
(and from the national MAH not to change/harmonise SmPC and to do the national application first)

Give in advance/before accession a clear timelines for the first RMS procedure !

# MRP/DCP-Applications in 2010 RMS



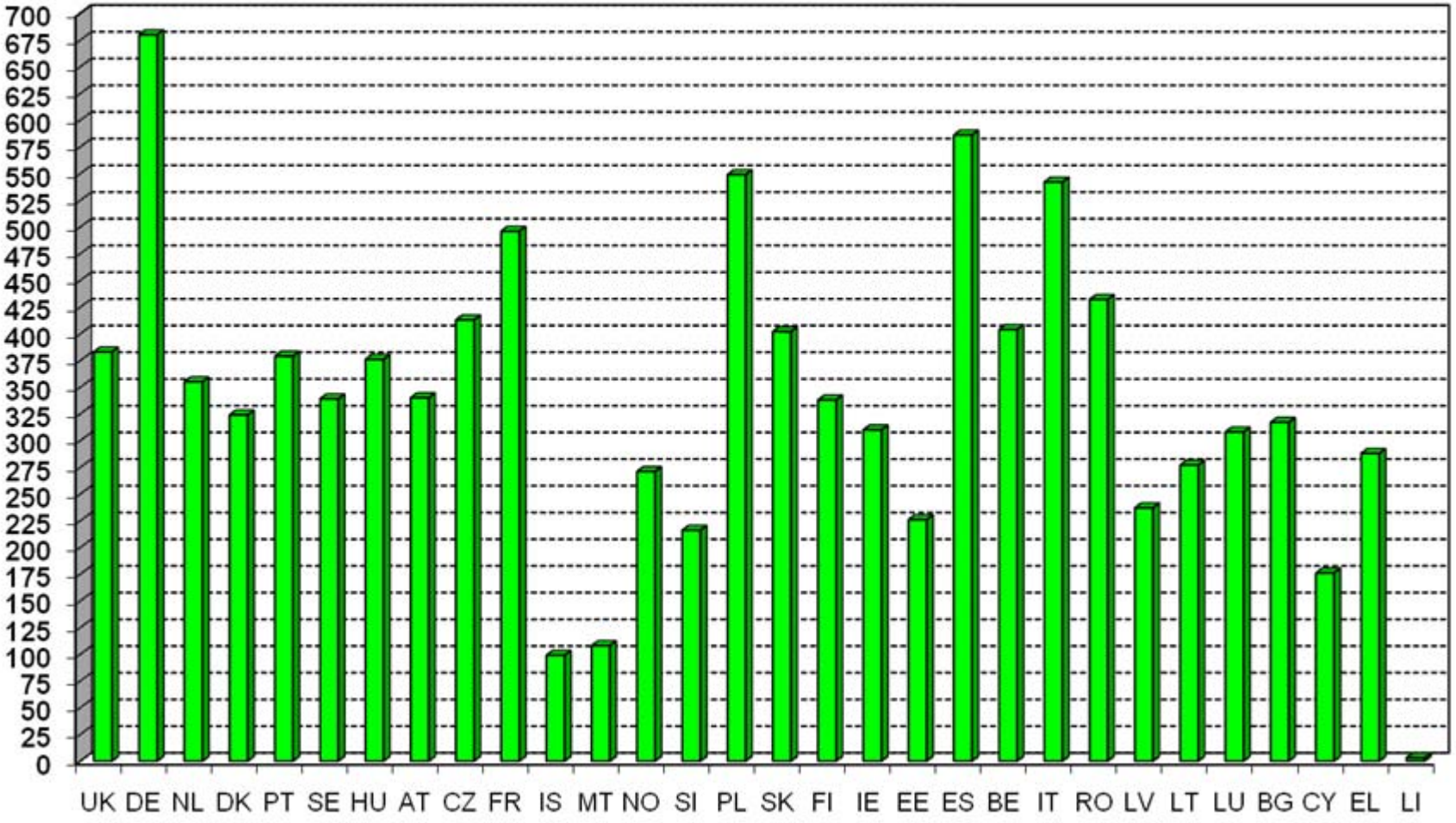

*Source: CMDh Press Release*



**26 MS as RMS**

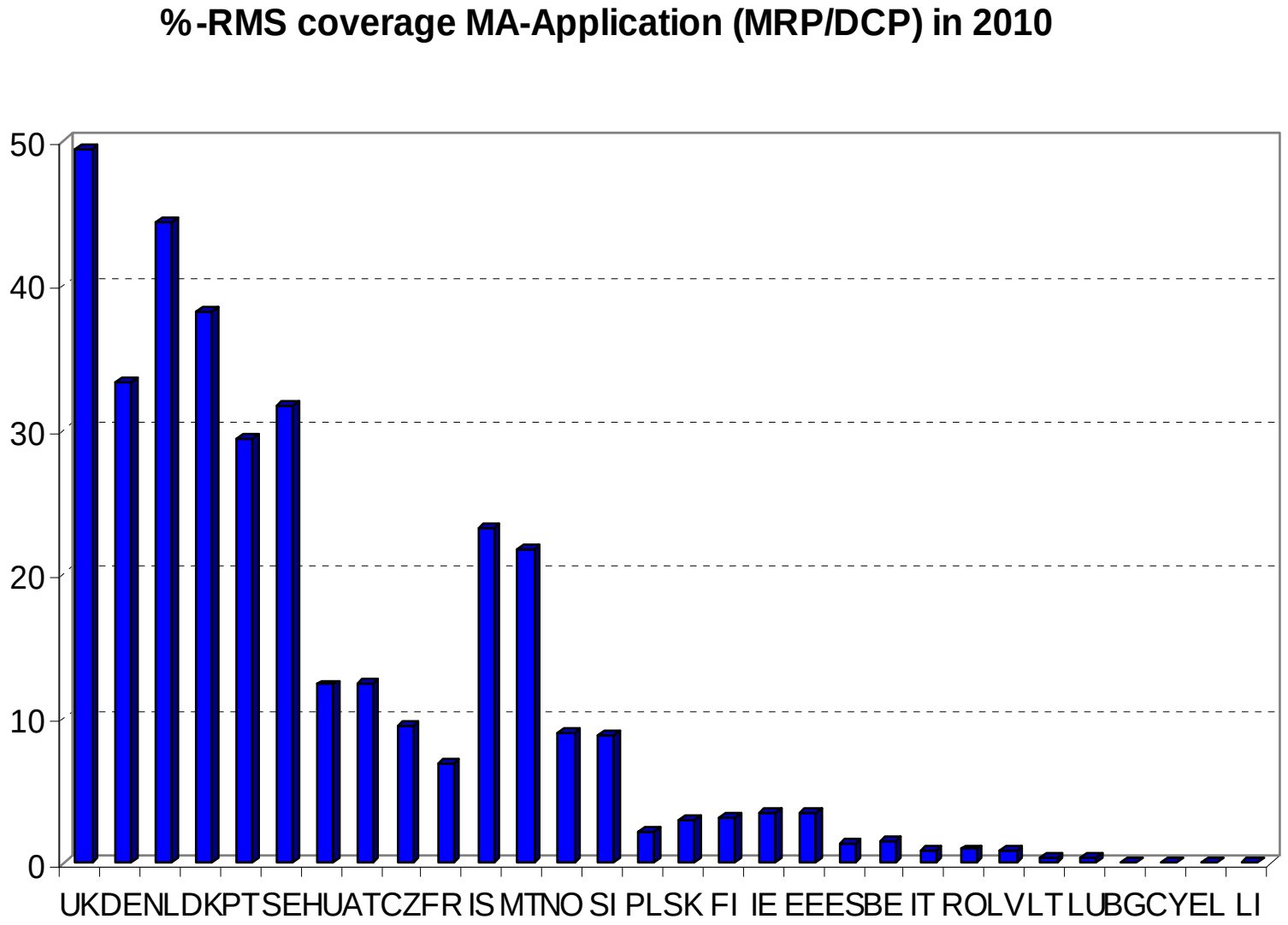
**6 MS are RMS for 80 % of all procedures!**

# MRP/DCP-Applications in 2010 CMS




*Source: CMDh Press Release*

# … the hidden message




*Source: CMDh Press Release*

# … the national world – next step

# Federal Institute for Drugs and Medical Devices (BfArM)

## … many thanks for your kind attention

*The BfArM is a Federal Institute within the portfolio of the Federal Ministry of Health*