Outcome and Benefit of Benchmarking – Expectations of the German Ministry of Health

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„Benchmarking“

Concomitant background

- benchmarking (with the element „regulatory structures“) is No 1 among the G-10 recommendations
- BCG-investigation „International Benchmarking on Innovation Performance of Pharmaceutical and Medical Industries and Health Care IT “ (supporting „Impulse Circle Health“ of „Chancellor-Initiative „Partners for Innovation“)
- restructuring of BfArM

What should be the value of benchmarking?

- organisation as part of a system or network learns to
  - look carefully and critically at its own standards
  - assess own standards and performances in comparison to those of similar organisations
  - improve by implementing what is generally accepted as good practice
- the system or network improves as a whole and reaches better communication, cooperation and understanding

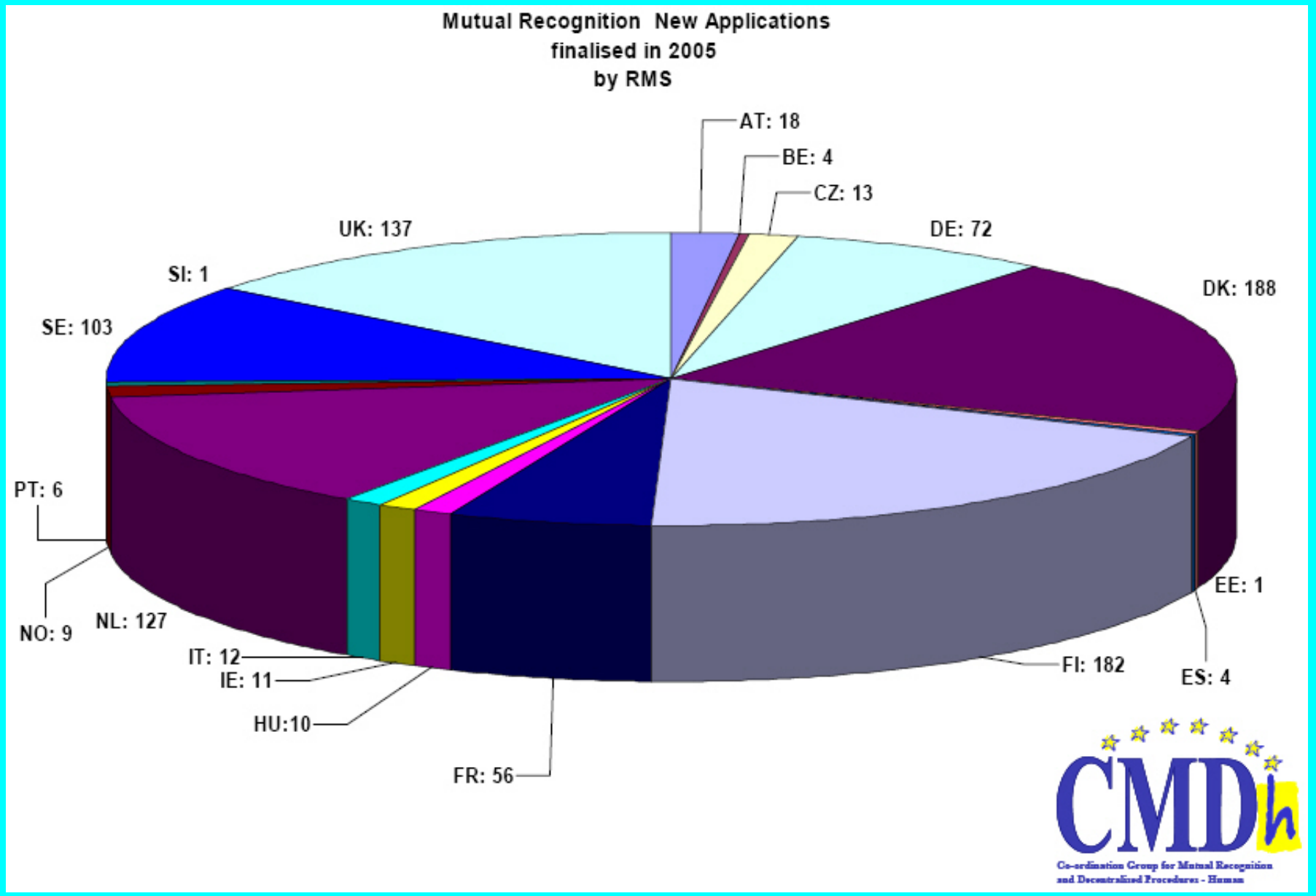
The aim of the EU benchmarking system is ...

- ”... to contribute to the development of a world class regulatory system for medicinal products based on a network of agencies operating to best practice standards.“
- to reach a ”common understanding of technical/regulatory requirements and consistency in interpretation and application, whether in the area of assessments, inspections or pharmacovigilance“

There may be good reasons to ...

- improve the overall performance of a network consisting of 42 institutions in countries with different traditions, experiences and markets

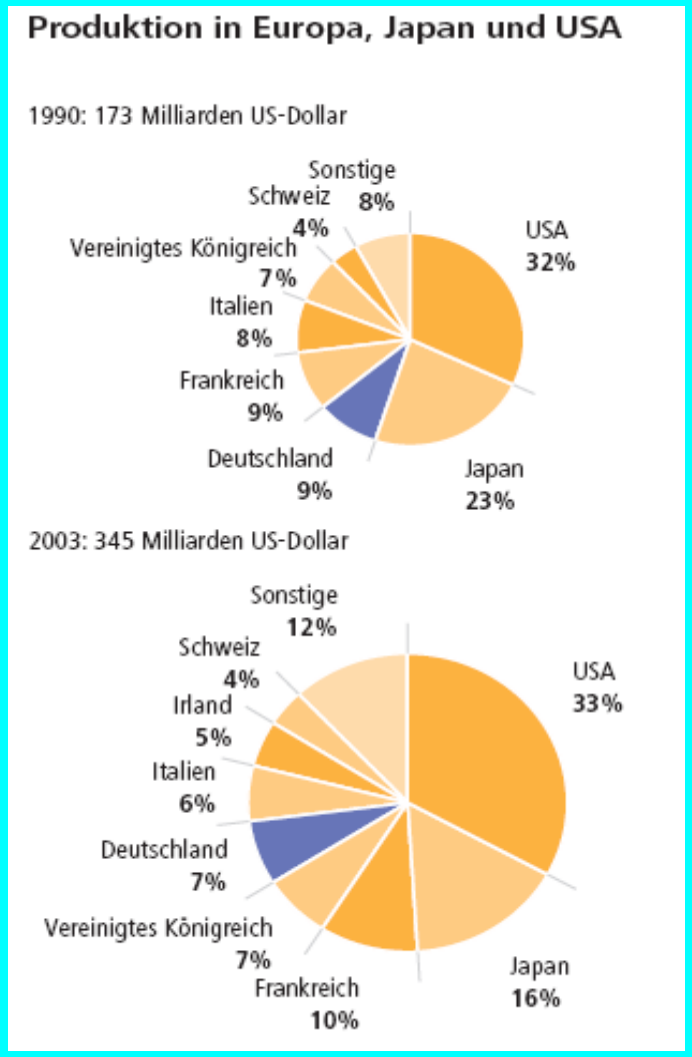

Austria
France
Latvia
Poland
Belgium
Germany
Liechtenstein
Portugal
Cyprus
Greece
Lithuania
Slovak Republic
Czech Republic
Hungary
Luxemburg
Slovenia
Denmark
Iceland
Malta
Spain
Estonia
Ireland
The Netherlands
Sweden
Finland
Italy
Norway
United Kingdom

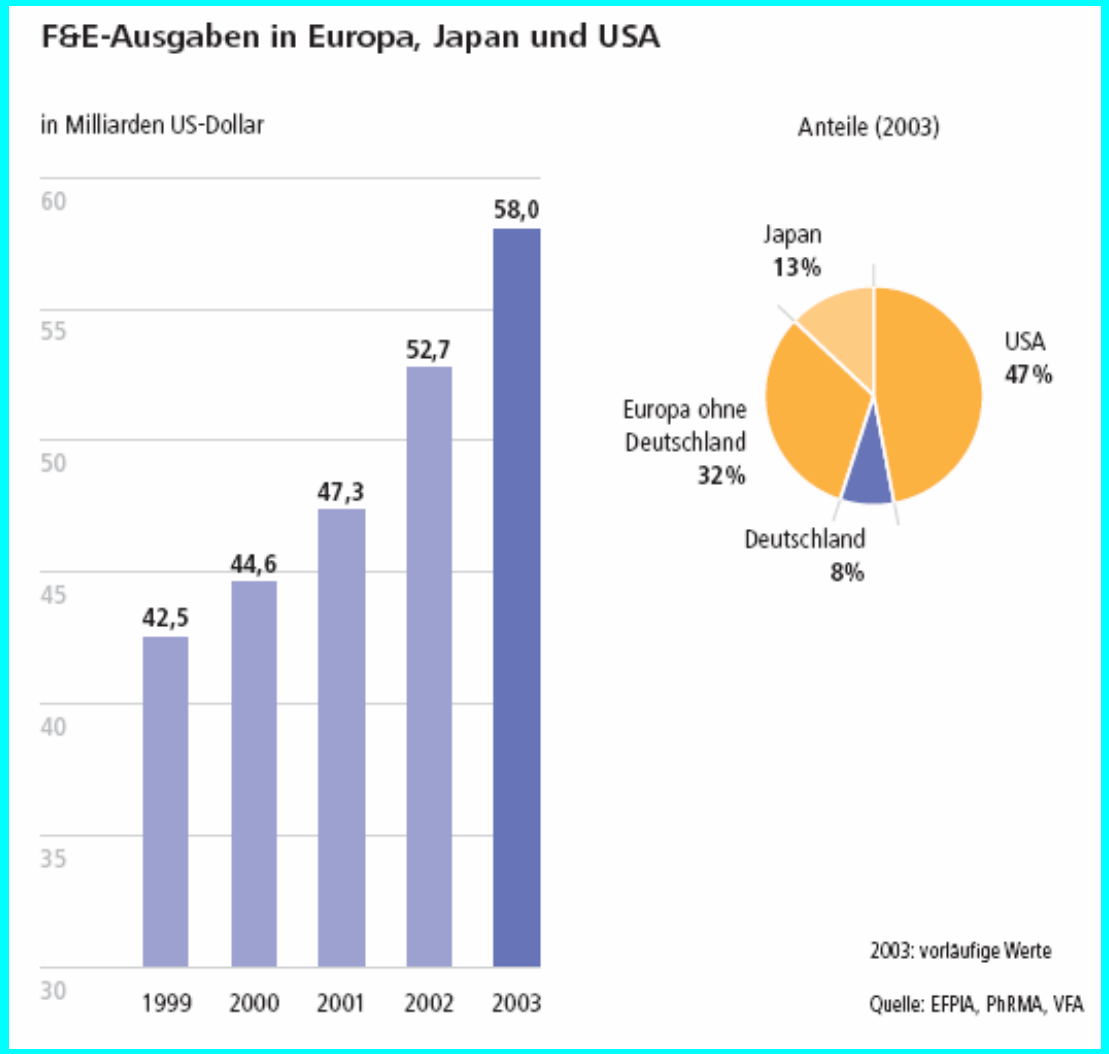

Mutual Recognition New Applications
finalised in 2005
by RMS
AT: 18
BE: 4
CZ: 13
DE: 72
DK: 188
EE: 1
ES: 4
FI: 182
FR: 56
HU:10
IE: 11
IT: 12
NL: 127
NO: 9
PT: 6
SE: 103
SI: 1
UK: 137
CMDh
Co-ordination Group for Mutual Recognition and Decentralised Procedures - Human

There may be good reasons to ...

- improve the overall performance of a network consisting of 42 institutions in countries with different traditions, experiences and markets
- support by good regulatory practice the development and production of medicinal products in a situation where R & D resources move outside the EU and new powerful competitors have entered the scene

Economic factor





What should be strived for:

- optimal structure and organisation
- adequate internal and external communication
- uniform interpretation of legal provisions
- fully standardized requirements imposed by the NCAs, to be met by the pharmaceutical enterprises
- coherent criteria to assess efficacy, safety and pharmaceutical quality
- consistent criteria for risk assessment, pharmacovigilance and inspections

However,

- as a whole, these goals will only be reached step by step
- concerning the individual organisation: ”The problem is less to get new ideas into your mind, but how to get the old ones out“
- concerning the system: There may be partly differing intentions, since the NCA network is not only cooperative, but also competitive

What does the German Ministry of Health expect?

EMEA and NCAs to

- agree on high-level indicators and specific performance indicators
- assess and compare, without prejudice, existing practices, experiences and views, find ”best–of“ and implement, at medium-term, fully comparable quality and risk management systems

What does the German Ministry of Health expect ?

of the NCA network:

- further increase in scientific expertise
- further intensifying of formal data exchange and overall communication within the network
- due sharing of overall workload between the NCAs, with regard to specific excellence
- reduce frictions in MR and decentralized procedures
- further strengthening of pharmacovigilance mechanisms and cooperation in safety matters

Expectations related to the German competent authorities

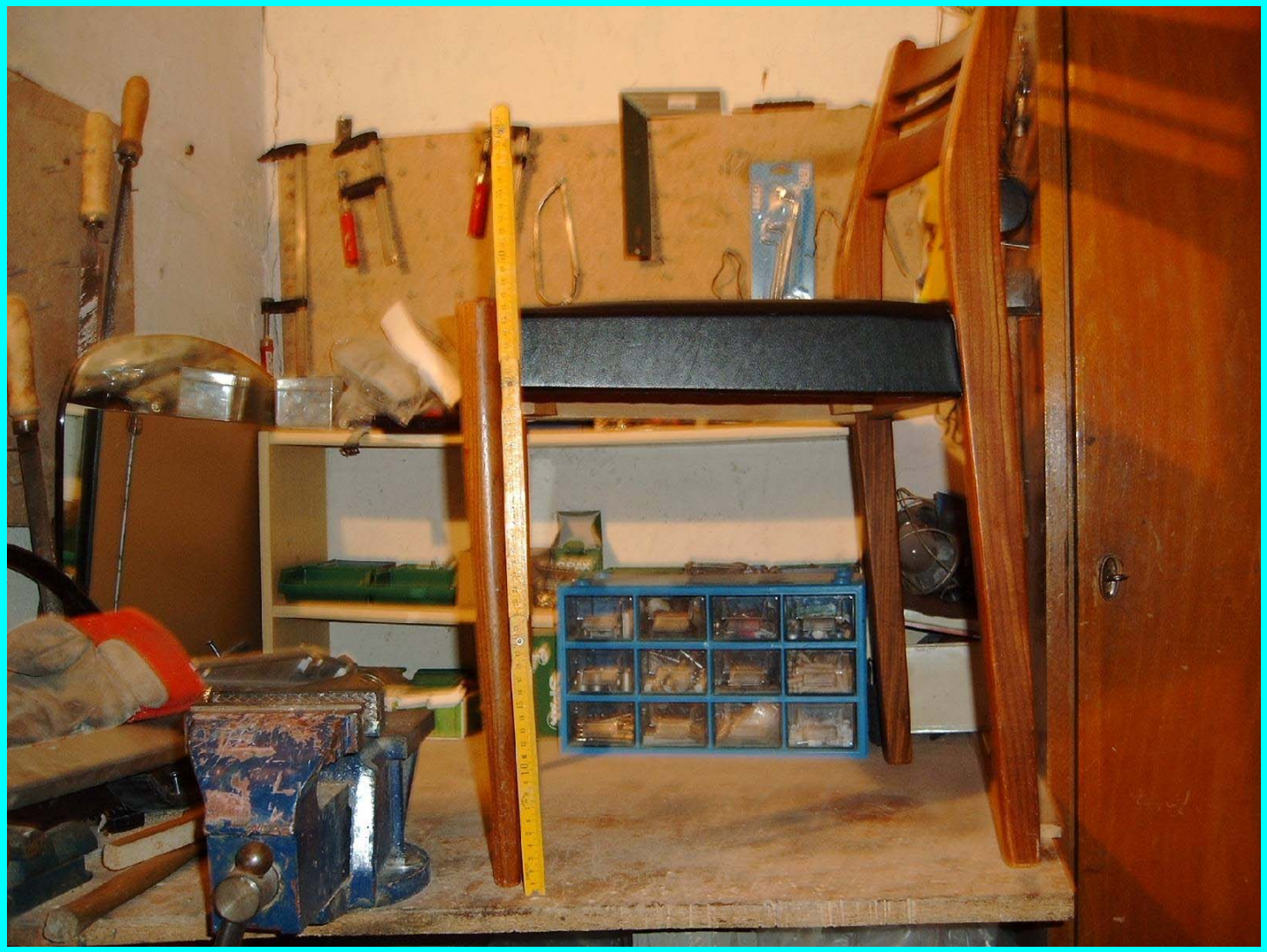
- find out about status-quo of own achievements und performances
- recognize own position in comparison with the other European NCAs
- gain internal acceptance and understanding for need of best practice
- further optimize structure and organisation
- consolidate own strengths
- address and reduce own deficits
- calculate fees that are adequate to the invested resources

Overall benefit for NCAs and industry:

- optimal use of resources / cost-adequate fees
- high-quality assessment
- timely decisions
- positive impact on mutual confidence and reliability
- progress in risk management adds to public image

„Benchmarking“ sounds important and is important, however,

- benchmarking is not a cookbook but a discovery process, and
- not a one-time but a continuous process
- there is a long way from analysis to maturity phase



Thank you for your attention!