

# 2001/20/EC – A European Directive?

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MAJOR REGULATORY OBJECTIVES FOR A REAL  
HARMONISATION IN EUROPE

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# Topics of non-harmonisation

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## **Submission Packages**

- High diversity of country-specific requirements
- No reliable and easy accessible information in English

## **Competent Authorities**

- Definition of CA
- Focus on review
- Accelerated review
- Schedule of assessment

# Topics of non-harmonisation

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## **Ethic Committees**

- Schedule of assessment
- Standards for (leading) EC

## **Cooperation Competent Authority/Ethics Committee**

- CA and EC procedures completely independent
- Evaluation in parallel but opinions/decisions are linked together
- Sequential procedures

AND

No arbitration and consensus finding procedure available

## Reasons for non-harmonisation

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- Insufficient instructions
- Available instructions give too much room for interpretation
- Disregarding instructions
- Different clinical practice

## Consequences of non-harmonisation

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- Delays in the start and finalisation of clinical trials
- High costs
- Delayed availability of medications in the market

# Objectives for improvement

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## **Administrative Burden**

- Reliable and easy accessible information regarding national requirements
- One standardised submission package

## **Assessment**

- Harmonised CA and EC assessment procedures in the Member States
- Establishment of quality assurance systems to ensure consistency of ECs
- Provision of pan-EU training for assessors and EC members to facilitate consistency in approach

## **Arbitration**

- Establishment of procedures for arbitration and consensus building on EU level

## Summary

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- Current procedures are far from harmonisation
- Consequences are high costs and delayed availability of medicinal products
- Europe's attractiveness for clinical research and global market competitiveness jeopardised