European Commission

ENTERPRISE DIRECTORATE-GENERAL

DGRA-Jahreskongreß
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Ansätze zur Reform des Europäischen Zulassungssystems

Nils Behrndt, LL. M. (Hull)
European Commission
Enterprise Directorate-General
Pharmaceuticals Unit (F2)

Structure

- *Review 2001*
- *Traditional herbal medicines*
- *Paediatric initiative*

Review - State of play in EP

- **Environment Committee** (ENV)
  - leading Committee
  - rapporteurs: Ms *Rosemarie Müller* for regulation, Ms *Grossetête* for the two Directives
  - rapporteurs presented reports on 3 June
- **Other Committees involved**
  - Agriculture and Rural Development (AGRI)
  - Budget
  - Industry, External Trade, Research and Energy (ITRE)
  - Budgetary Control

Review - State of play in Council

- **Working Party**
  - first discussions in December 2001
  - number of meetings under Spanish Presidency
  - "horizontal approach": parallel discussion of 3 proposals
  - progress not as fast as expected
- **Council**
  - Health Council on 26 June
  - two points on agenda: scope and management board

Review - scope of CP

- **fundamentals of two-tier system**
  - both procedures delivered satisfactory results
  - in-built subsidiarity in centralised procedure (experts)
- **Why centralised procedure?**
  - thorough assessment of sensitive products on EU level
  - access to innovative medicines
- **competition of procedures**
  - incentive for permanent improving
  - overriding causes can exclude competition

Review - scope of CP

- **COM proposal**
  - CP *obligatory* for new therapies & new active substances
  - CP *optional* for other products of significant innovation
- **EP**
  - ENV: no amendments by rapporteurs
  - *Scapagnini* (ITRE), *Sturdy* (AGRI): in favour of optionality
- **Council**
  - divergent views
  - one of two topics on agenda of Health Council of 26 June

Review - MRP and arbitration

- **COM proposal**
  - MRP: shorter deadlines, decentralised procedure, harmonised legal status
  - arbitration: "serious risk", co-ordination group, forced arbitration, intermediate marketing, obligation of all MS
- **EP**
  - ENV, ITRE, AGRI: no or no major amendments
- **Council**
  - overall support
  - some concern about reduced time-limits and legal status

Review - validity of authorisation

- **COM proposal**
  - central and national MA valid *indefinitely*
  - but MA *ceases to be valid* if no marketing within 2 years
- **EP**
  - *Grossetête* (ENV): deadline for "sunset" should be 3 years; exceptions should be provided
  - *Read* (ITRE), *Sturdy* (AGRI): against sunset clause
- **Council**
  - some MS would like to keep renewals
  - sunset clause opposed by some MS

Review - pharmacovigilance

- **COM proposal**
  - reinforced competencies for immediate action
  - shorter intervals for PSUR
- **EP Environment Committee**
  - *Grossetête*: no comments
  - *Müller* : "red triangle" for new medicines; patient reports
- **Council**
  - general support
  - some MS question need for more frequent PSUR

Review - data protection/generics

- **COM proposal**
  - always 10 years plus possibly 1 additional year
  - clarification of generic application plus "Roche-Bolar"
- **EP**
  - ENV: no amendments proposed by rapporteurs
  - ITRE: authorisation after 8, marketing after 10 years
  - AGRI: usage patents; "biotech generics"
- **Council**
  - general support for "Roche-Bolar"
  - dissenting views on details of data protection

Review - information to patients

- **COM proposal**
  - allow test-case of information to patients for certain products under strict conditions
- **EP**
  - *Grossetête* (ENV): tighten control by EMEA, no deadline, no self-regulatory control by industry, funding for EMEA
  - *Read* (ITRE): against proposal, but for reflection
- **Council**
  - no detailed discussion yet

Review - Further planning

- **First reading**
  - vote in EP Environment Committee beginning of July 2002?
  - vote in EP plenary session in October 2002??
  - common position - Health Council in November 2002???
  - Danish Presidency might change to "vertical approach"
  - no deadlines for first reading!
- **Second reading?**
- **Conciliation phase?**

Traditional herbal medicines

- **Why?**
  - existing framework not 100% appropriate ⇨ grey zone
- **Contents?**
  - simplified registration if plausible info on safety/efficacy
  - criteria: herbal medicines ≥ 30 years, OTC indications
  - new herbal committee
- **State of play?**
  - first discussion in Council Working Party on 10 June
  - first discussion in ENV on basis of report in July 2002

Paediatric initiative

- **Why?**
  - urgent need for children specific research/medicines
- **Contents?**
  - regulatory incentives
  - network of data and documentation
  - research funding
- **State of play?**
  - external consultation concluded
  - legislative proposal under preparation

Other legislative initiatives

- **Review of Annex I to Directive 2001/83**
  - external consultation until 17 June
  - adoption by comitology during 2nd half 2002
- **Variations regulations**

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