Reform des Zulassungssystems von Arzneimitteln in der EU -

Position der EU Kommission

DGRA Jahreskongreß

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Birka Lehmann
EUROPEAN COMMISSION
Enterprise Directorate-General
Pharmaceuticals Unit (F2)

Under Review/Discussion

→ Amendment Regulation 2309/93/EC

→ Amendment Directive 2001/83/EC

(→ Amendment Directive 2001/82/EC)

Erkki Liikanen, Press Conference, Brussels, 18 July 2001

Objectives of the Amendments

→ To define principles of protection of subjects

→ To define procedures and time frames

Proposal for
Regulation 2309/93/EC

Article 3 and Annex 1 (Scope)

→ 'all new active substance'

or

→ 'entirley new active substance' (Recital 8)

⇒ still under discussion

Proposal for
Regulation 2309/93/EC

Small and medium size companies

Recital 8, 20 : Provision ... for small and medium size companies

Management Board provide help

Fee reduction

Proposal for
Regulation 2309/93/EC

http://pharmacos.eudra.org/F2/pharmacos/docs.htm#news

- **Study on innovation in the pharmaceutical area**
  In 2002 the European Agency for the Evaluation of Medicinal Products, which is in charge of this centralised procedure, noted that there was a significant drop in the number of applications for marketing authorisations concerning new chemical entities.
- In order to identify what lies at the root of this phenomenon, to measure its actual size and to propose measures to halt it, the Commission has decided to launch a study to answer the following questions:
- - Is there a worldwide crisis in innovation in the pharmaceutical sector?
  - What are the reasons behind this crisis?
  - What tools do we have available to kick-start innovation?
- The call for tender was published on the 3rd of May 2003 in the OJEU 2003/S 86-076424; electronic copies can be found here; paper copies can be requested at the following address : patrick.accart@cec.eu.int. The deadline for submission is 03/06/2003

Proposal for
Directive 2001/83/EC

Generic medicinal products

→ Data Exclusivity

→ Reference medicinal product in the EU

→ Bolar provision

→ Usage patents

→ legal status … taken seriously into account in MRP

Proposal for

Directive 2001/83/EC

Generic medicinal products

→ …same qualitative and quantitative composition in active principles and same pharmaceutical form….different salts, esters, isomers, mixtures of isomers, complexes or derivaties of an active substance are considered as the same active substance, unless they differ significantly

→ Where a biological medicinal porduct which is similar to a reference biological product does not meet certain conditions in the definition of generic medicinal products, results…

Proposal for

Regulation 2309/93/EC
Directive 2001/83/EC

Marketing Authorisation

→ New procedures – new time lines

→ Availability of information on the medicinal product

Proposal for

Regulation 2309/93/EC

Directive 2001/83/EC

Authorisation Procedure

- Acceleration by shortening deadlines
- Implement fast track procedures for products of major interest
- Implement conditional authorisation (to be re-evaluated on a yearly basis)
- Maintain authorisation under exceptional circumstances
- EC to adopt recommendations to be applied by MS´s regarding compassionate use

Proposal for
Regulation 2309/93/EC
Directive 2001/83/EC

Authorisation Procedure

- Mutual Recognition Procedure

- Decentralised Procedure → Harmonisation pre-authorisation

Proposal for

Regulation 2309/93/EC

Directive 2001/83/EC

Accelerated and simplified decision making process

- MS´s will only have 15 days to react to EC proposal
- EC procedure streamlined (reference to articles 3 and 5 of decision 1999/468/EC instead of regulatory procedure)
- EC shall prepare a draft decision within 30 days of receipt of the opinion

Proposal for
Regulation 2309/93/EC
Directive 2001/83/EC

Maintance

Renewal

→ one renewal after 5 years

Sunset clauses

→ Placing the medicinal product on the market within 3 years

→ When an authorised medicinal product previously placed on the market is no longer actually present on the market for 3 consecutive years, the authorisation shall cease to be valid.

Proposal for
Regulation 2309/93/EC
Directive 2001/83/EC

Maintance

Pharmacovigilance

→ PSUR every 6 months .. Following the initial placing on the market (in the Community)

→ Agency may request that specific pharmacovigilance data be collected

The holder of a marketing authorisation shall not be authorised to communicate information concerning pharmacovigilance issue to the general public without the consent of the Agency

Proposal for
Regulation 2309/93/EC
Directive 2001/83/EC

Referrals

- Try to avoid arbitration ("best endavours")
  → Coordination Group (60 days)
- Once referred, allow marketing in positive MS´s
- Reduce time from 90 to 60 days
- Shorten decision making process
- Summary of Product Characteristics – Harmonisation

Proposal for
Regulation 2309/93/EC
Directive 2001/83/EC

Serious Potential Risk to Public Health

Definition requested in review 2001/83/EC

Article 29 (1a)

Guidelines to be adopted by the Commission shall define a serious potential risk to public health

Proposal for

Regulation 2309/93/EC
Directive 2001/83/EC

Committees
and
members in committees

Proposal for

Regulation 2309/93/EC
Directive 2001/83/EC

EMEA

Management Board, Advisory Board

CHMP*, CVMP*, COMP, Herbal

- working parties, expert groups, panels
- *may establish scientific advisory groups

Member States

Co-ordination Group

Proposal for

Regulation 2309/93/EC

Directive 2001/83/EC

Management Board	15 Members appointed by the Council (2 Members from industrial associations, 1 from patients‘ organisations, 1 from doctors‘ organisation, 1 shall represent social security schemes)
Advisory Board	1 Member per Member State
CHMP/CVMP/Herbals	1 Member per Member State appointed by Executive Director (5 additional members)

Proposal for
Regulation 2309/93/EC
Directive 2001/83/EC

Coordination Group

1 Member per Member State

MS´s to forward a list of products for harmonisation (SPC) to coordination group each year

Proposal for
Regulation 2309/93/EC
Directive 2001/83/EC

The Commission or a Member State, in agreement with the Agency and taking into account the view of of the interested parties, may refer these products in accordance with paragraph 1.

Selection Member State

Selection Coordination Group

Selection Commission/Member State/Agency

‚interested parties'

C(P)MP

Proposal for
Regulation 2309/93/EC
Directive 2001/83/EC

Where we are?

→ On-going discussion in EU Council

→ EU Parliament - second reading (?)

Time constriction?

Finalising the review process before enlargement May 2004

OR

Re-opening the discussion with all 25 Member States after enlargement