E·C·H·A·M·P

Introduction of **ECHAMP**

(European Coalition on Homeopathic and Anthroposophic Medicinal Products)

Homeopathic Workshop
EMEA London
October 27, 2006

E·C·H·A·M·P

Members

- Full Members (50)
  - In 14 EU Member States
  - Pharmaceutical Companies
- Associated Members (10)
  - National Manufacturers Associations

E·C·H·A·M·P

Structure & Bodies

- Membership Assembly
- Board of Management
- General secretary
- Office staff in Brussels
- Working parties (6)
- WP Regulatory Affairs: 5 subject groups
- > 50 meetings/year

E·C·H·A·M·P

Aims & Key-Words

- **Aims**
  - Appropriate legislation
  - Appropriate regulatory environment
- **Key-words**
  - Quality, safety & effectiveness
  - Harmonisation & free circulation
  - SME, Lisbon Strategy
  - Proportionality & pragmatism

Vision EU Environment

Legal and Regulatory Frame for Homeopathic and Anthroposophic Medicinal Products
The way from 2004 → 2008 →2012

To be achieved on European and on Member State level

	Article 14 : SSRP	**Article 16 : MA**
Directive 2001/83/EC,	Yes	Article 16 unique = a European 16.2
Annex I (general rules for the proof of quality, safety and efficacy)	Adequate rules for the proof of quality, safety	Adequate rules for the proof of quality, safety **and effectiveness**
Notes for Guidance	Amongst others: Definitions Stability Safety Viral safety And others	Safety & Quality plus Long-term experience of use 'Well-established or Traditional' Effectiveness Etc.
NTA→ CTD	**Adapted and harmonised CTD**	
Assessment by Regulatory Authorities	Mutual Recognition & Harmonised assessment criteria	Mutual Recognition & Harmonised assessment criteria

www.echamp.org

Perspective workshop

- Thank you
- High expectations
- Progress necessary
- Questions ……. answers