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Introduction of **ECHAMP**

(European Coalition on Homeopathic and
Anthroposophic Medicinal Products)

Homeopathic Workshop

EMA London

October 27, 2006

Members

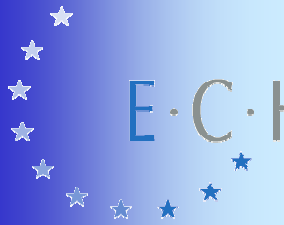
- ◆ Full Members (50)
 - In 14 EU Member States
 - Pharmaceutical Companies

- ◆ Associated Members (10)
 - National Manufacturers Associations



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



Aims & Key-Words

◆ Aims

- Appropriate legislation
- Appropriate regulatory environment

◆ Key-words

- Quality, safety & effectiveness
- Harmonisation & free circulation
- SME, Lisbon Strategy
- Proportionality & pragmatism



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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



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Perspective workshop

- ◆ Thank you
- ◆ High expectations
- ◆ Progress necessary
- ◆ Questions answers