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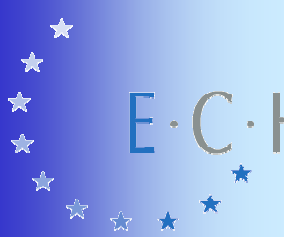
Conclusions of **ECHAMP**

(European Coalition on Homeopathic and
Anthroposophic Medicinal Products)

Homeopathic Workshop

EMA London

October 27, 2006



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Way Forward (I) – Subject?

Medicinal products

- ◆ Specific therapeutic systems: Homeopathy
- ◆ 200 resp. 90 years of EU tradition



Way Forward (II) – What to Do?

- ◆ Fill in the gaps and amend deficiencies in legislation (See the Commission Report 1997)
- ◆ Establish a harmonised & specific regulatory environment
- ◆ Make a MRP/DcP functioning: guidelines & guidance on all the key-information of a dossier (20% - 80%)



Vision

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	Harmonised assessment criteria	Harmonised assessment criteria

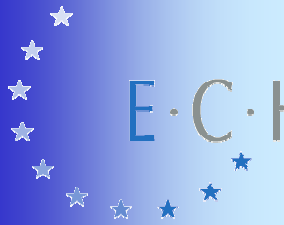


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Way Forward (III) – How?

A strong European Working Group

- ◆ Clear and sufficiently strong mandate
- ◆ Support from a central European Body
- ◆ Experts to be involved
- ◆ Transparent working procedures



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Way Forward (IV) – Key Words

- ◆ Quality, safety & effectiveness
- ◆ Harmonisation & Free circulation
- ◆ SME, Lisbon Strategy
- ◆ Proportionality in primary & secondary legislation (regulation without over-regulation)
- ◆ Take into account the peculiarities
- ◆ Pragmatic approach (New Swiss legislation)



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www.echamp.org

- ◆ Thank you
- ◆ Our expectations
 - Progress
 - Will to contribute
 - Growth & employment (aims of Lisboa)
- ◆ Concrete outcome of today?