



The precarious status of herbal products in the EU

Presentation to the EP Interest Group on CAM
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by

The Herbal Working Group of the CAM Stakeholder Group

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Also on behalf of:

EHTPA - European Herbal & Traditional Medicine Practitioners Association

EITAM - European Initiative for Traditional Asian Medicine

Use of herbals in the EU

- Market reports consistently show herbal medicine most popular form of complementary medicine used in Europe
- Germany and France = market leaders
- Herbal medicines widely used across the EU e.g. 2009 UK MHRA^{*} showed that over a quarter of the UK population had used a herbal remedy in the previous 2 years
- Consumers relying on the legislators to provide them with a full range of traditional herbal medicines. Failure to achieve this will force consumers to buy from unreliable internet sources or back-street traders

^{*} Ipsos MORI, 2009

EC Directive 2004/24/EC

Traditional Herbal Medicinal Products Directive - THMPD

- Original goal of THMPD: safe and ready access to traditional herbal medicinal products (THMPs) in the EU. To date only around **200** THMPs in 27 MSs registered since 2004.
- The THMPD has failed to provide for THMPs from systems of traditional medicine, such as Ayurveda (from the Indian subcontinent) or traditional Chinese medicine (TCM).
- THMPD does not clearly define the borderline between traditional herbal medicines and botanicals in food supplements



Lack of regulation affects consumer safety: The risk of 'falling between 2 stools'



Registered
THMPs

Borderline
problem

Legal
food
supps

Unregulated products,
unlicensed medicines,
unauthorised novel foods

Asian Traditional Medicine

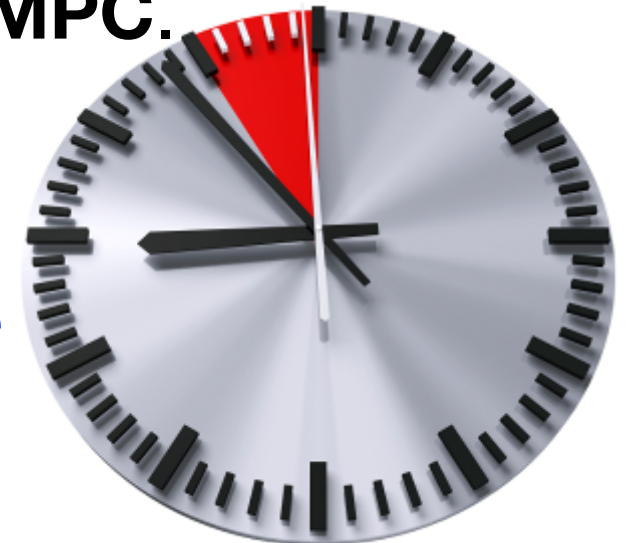
- Asian Traditional Medicine systems have been practised in Europe for several decades.
- **Traditional Chinese medicine (TCM), Indian medicine (Ayurveda).** Tibetan Medicine, Japanese Traditional medicine (Kampo), Vietnamese medicine, Unani medicine, Thai medicine, Korean medicine etc.



Full implementation of THMPD

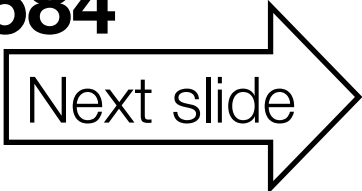
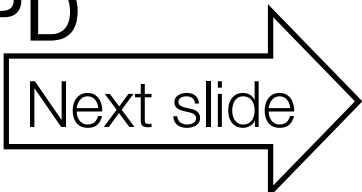
30 April 2011 – more time required

- To-date only ~ 200 registrations in 27 MSs (estimated < 50 spp plant)
- THMPD operates a **cut off date** for those traditional herbal medicinal products, which were already on the market when Directive became law in 2004. The seven-year transition period expires on 30 April 2011. Many herbal products will be disbarred from the market.
- The number of THMP-registrations only started to pick up in the last 2-3 years. The first 3-4 years of the 7 year transition period were mainly used to **establish the guidelines within the HMPC.**
- Given the severe obstacles to THMP registrations, can the EP gain an **extension of the transition phase** of the THMPD beyond the 30 April 2011 deadline?



MEP action points



- To follow-up on the key EC **experience report COM(2008)584**

- To propose **reform of the duties of the Herbal Medicinal Products Committee** (HMPC) under the terms of the THMPD

- The EP should request of the EC and EFSA to clarify **the borderline** between traditional herbal medicines and botanicals in food supplements
- Given the severe obstacles to THMP registration, can the EP **extend the transition phase** of the THMPD beyond the April 2011 deadline?

To follow up on European Commission experience report COM(2008)584

- HMPC should increase production of monographs.
- Clarification required how simplified registration can be extended to include other medical traditions
- Amendment of the THMPD to allow inclusion of non-herbal ingredients in traditional medicines
- Amend the 15-year usage restriction to admit satisfactory evidence of safe traditional usage outside the EU for the total 30-year period

To reform the duties of the HMPC

- HMPC needs to adopt a broader interpretation of
 - ▶ quality requirements,
 - ▶ eligibility of herbal,
non-herbal,
mineral and
food ingredients

Goal: to encourage substantially more registrations

- To achieve this additional resources are needed

Patients and CAM-health care providers need a full range of THMPs



MEP action: facilitate development of new framework
for OTC and prescribed products
(as per EC experience report 2008)

More information ?

- MEP Action Points



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Thank you!