The precarious status of herbal products in the EU

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by
The Herbal Working Group of the CAM Stakeholder Group
Presenter: Robert Verkerk PhD - Alliance for Natural Health International
Also on behalf of:
EHPTA - 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’

Borderline problem

Registered THMPs

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

Contact point:

CAM Interest Group back-up office
c/o Dr Ton Nicolai
ECH, Chaussée de Bruxelles, 132, box 1
1190 Brussels, Belgium
e-mail: info@cam-interestgroup.eu

Thank you!