



Investing in health Investing in CAM

The availability of herbal medicines
throughout the EU

Presentation from EUROCAM

Michael McIntyre, UK - 27/6/13



THPMD scope needs widening

Food supplements and medicines need clearer differentiation

- Directive 2004/24/EC, the Traditional Herbal Medicinal Products Directive (THMPD), is **a significant step in the regulation of herbal products (THMPs)** but has certain shortcomings.
- The scope of the THMPD needs to be widened to make available a full range of herbal and traditional CAM medicines for qualified practitioner use throughout the EU. Food supplements fall short of the strength and quality for medicinal use; they are not suitable for treating sick patients.
 - EUROCAM asks the Commission and European Parliament (EP) to work with the Member States (MS) to **clarify how a full range of traditional herbal medicines can be registered under the THMPD.**
- **Going forward:** considerable work is still needed to provide an appropriate legislative framework to make available all those herbal medicines required for qualified practitioner use throughout the EU.

THMPD needs integrated implementation across the EU

- Ingredients of THMPs can be herbal substances, herbal preparations and minerals. This is currently interpreted and applied differently by MS. EUROCAM asks that the national competent authorities as well as the Herbal Medicinal Products Committee (HMPC) are **provided with clear guidance** as to how these criteria should be interpreted. Examples of materials whose use needs elucidation are
 - Minerals and other ingredients which are commonly used in a traditional system of medicine
 - Common foods such as honey, ghee, propolis etc.
- To date implementation of the THMPD throughout the EU is patchy. The UK, Poland, Germany and Austria have granted the majority of THMP registrations. Although the number of registered THMPs is slowly increasing, there are still MS that have only registered a few THMPs. Those MS that are slow in implementing the Directive need **encouragement and monitoring**.
- Directive 2001/83/EC stipulates that MS should take 'due account' of positive decisions taken by one MS on a THMP. EUROCAM welcomes the fact that, the process of mutual recognition (MRP) is now underway for THMPs and recommends that this MRP uptake is **monitored and encouraged**.

Use existing legislation to make available full range of traditional medicinal products for qualified practitioner use

- To date only few THMPs from other medical traditions (especially Asian medical traditions) have been registered which leaves many THMPs unregistered and thus inaccessible for the treatment of patients by qualified practitioners. The Commission itself has acknowledged this deficit of the THMPD in a Communication to the EP in 2008.
- EUROCAM submits that the current limited range of possible indications by the HMPC **is open to broader interpretation**. At present, Directive 2001/83/EC determines in Art 16a.1 (a) that THMPs *'have indications exclusively appropriate to traditional herbal medicinal products which, by virtue of their composition and purpose, are intended and designed for use without the supervision of a medical practitioner for diagnostic purposes or for prescription or monitoring of treatment.'*
- EUROCAM nevertheless considers that the range of indications appropriate to THMPs **can easily be extended**, without violating the intentions of Directive 2001/83, Art 16a. This can be achieved by the simple expedient of designating particular formulations as for use by *'an authorized health professional'* which proviso is already in use in Article 5.1 of Directive 2001/83/EC.

Using all available sources of evidence (traditional use & scientific data) for HMPC monographs

- At present the restrictive copyright regime within EMA presents a barrier to the scientific evaluation of the monographs by the HMPC.
- EUROCAM submits that the **HMPC should have the authority to use all sources of relevant scientific evidence** to support their monographs, including those derived from published texts, peer-reviewed journals and the respective *materia medica* and pharmacopoeias of traditional herbal medicine systems.

- The THMPD is an important first step
- We have to make THMPs a success throughout Europe
- HMPC and MS need support and guidance from Commission and Parliament
- **EUROCAM is delighted to work with the Commission and EP in making herbal medicine safely available throughout the EU**

