EPP Group
in the European Parliament

CAMIG
MEPs for CAM

Herbal medicinal products

General comments with reference to the Matrix report

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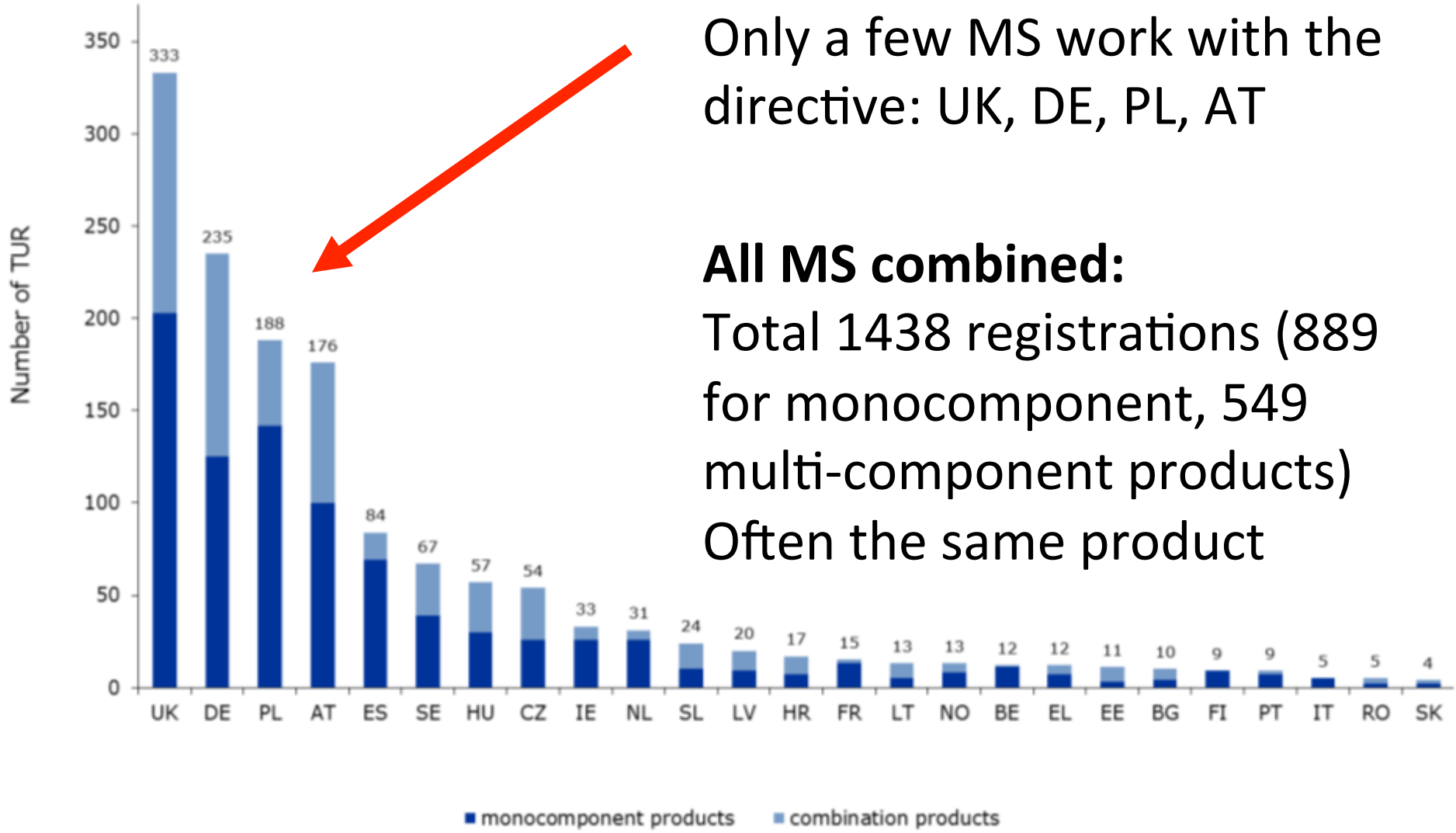
Plants as Medicines

- Herbal Medicine - Phytotherapy
- Traditional European Medicine
- Traditional Chinese Medicine
- Ayurveda
- Tibetan Medicine
- and many more…

Directive 2004/24/EC

- Traditional Herbal Medicinal Products (THMP)
- **2004/24/EC was thought to be a landmark decision for CAM products**, and the hope was expressed, that from now on this category of herbal products **will ensure the availability throughout Europe**.

Situation after 10 years



Only a few MS work with the directive: UK, DE, PL, AT

All MS combined:
Total 1438 registrations (889 for monocomponent, 549 multi-component products)
Often the same product

DG SANTE comments:

… However it is explained that this does not necessarily imply that the herbal products are not on the market, as they may be available as medicinal products authorised by a marketing authorisation or, for instance, food supplements. The conclusion is made there are no acute availability problems. …

(Letter of DG SANTE to EUROCAM 22 June 2015)

A difference

- Food supplements
  - Help to maintain function of the healthy body
  - Prevention, improve health
- Medicines
  - Health problems,
  - Treat diseases

Health professionals and patients need medicines to treat illnesses and health problems.

HMPC: a coordinating body at EMA

Directive 2004/24/EC established the Herbal Medicinal Product Committee (HMPC) at the European Medicines Agency (EMA):

- It does its best to unify the different national MS standpoints.
- The HMPC prepares monographs and guidelines for registration.

Despite the good work within the HMPC, the MS are far from applying these guidelines in a coherent manner. As a result THMPs registered in one MS face difficulties when an application is filed in another MS using the same data.

Despite the fact that the unified HMPC guidelines are in place, the national competent authorities often interpret them in completely different ways.

Clarifying the borderline between Food and Medicine

Some MS classify herbal products as Food Supplements (FS).

- regulated by the European Food Safety Authority (EFSA);
- are intended to improve health and contribute to the normal function of the body. In the light of this definition FS cannot replace medicines;
- MS following this approach do not register any THMPs;
- The Commission has so far not clarified this situation.

The potential of the THMP registration scheme can only be achieved if the therapeutic scope and differences as well as the borderline between herbal products marketed as food supplements and herbal medicines is clarified.

How to address the shortcomings Strengthening the role of HMPC

2004/14/EC: MS should take 'due account' of positive decisions taken by another MS.

Currently positive decisions on THMP-registration taken by one MS are more often than not ignored by other MS for no apparent reason.

For a harmonised market the HMPC needs support to:

- **strengthen its coordinating power with respect to the MS;**
- **guide MS to adopt a consistent application of the THMP scheme;**
- **clarify the 'due account' rule;**
- **make the scope of THMP registrations more flexible.**

How to address the shortcomings Mutual Recognition Procedure (MRP)

For more than a year there has been an agreement that THMPs can enter a MRP on a voluntary basis. Here again the HMPC guidelines should facilitate mutual recognition. In fact, the MRP procedure results in controversy, and thus this route of THMPs registration remains difficult.

- **To monitor MRP progress, identify obstacles and encourage the MRP procedure.**

How to address the shortcomings Broadening the indications

The current interpretation of possible therapeutic indications is limited.

> 2004/24/EC: 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."

To encourage the HMPC to broaden the indications for THMPs.

The scope of indications for THMP could be extended to "after being diagnosed by a physician or health practitioner." Such wording is already in use in some MS.

Outlook:
Extension of Directive 2004/14/EC

To further strengthen the position and availability of CAM medicines in Europe an initiative is necessary to broaden the scope of Directive 2004/14/EC. The Commission clearly recognised the shortcomings already in 2008. It reported:

> " Medical traditions such as those mentioned above (i.e. traditional Chinese medicine , Ayurveda etc) are based on a holistic approach, and the set of requirements for the simplified registration procedure under Directive 2004/24/EC is not appropriate for a global regulation of such medical practices. …
>
> **Nevertheless, independently of this report, the suitability of a separate legal framework for products of certain traditions should be assessed."**