



Position paper of EUAA (& ANME) regarding THMPD and the European Petition

November 2010

Currently, a petition called “Stop THMPD” is collecting signatures to be presented to the EU Commission. The aim is to prevent the amendment 2004/24/EC of Directive 2004/83/EC regarding the registration of traditional herbal medicinal products into force on April 30, 2010. The petition claims that after the end of the transition period all herbal products not yet registered as a medication will be banned, and the EU consumer will lose the right of choice of natural products. As an example, the petition points to peppermint which is considered a medicinal plant in the treatment of irritable bowel syndrome. Unfortunately, the choice of arguments is clearly far from realities, which is why the EUAA refrains from supporting the petition.

The EUAA is clearly supportive of the approach of improving product quality and consumer safety by registering the preparations as traditional medicinal products.

This said, the EUAA also recognizes that the current rules of drug registration make a major part of Ayurvedic remedies ineligible for registration. At the same time the possibilities of marketing such products as food supplements are drawing towards an end due to the very strict conditions of health claim approvals, which may effectively close both approaches, the status as supplement and the status as a drug.

What will happen on 30th of April 2011?

With the background of a growing market of health products with more or less uncontrolled quality the EU has created a possibility of simplified registration of herbal medicinal products. The usually demanded dossiers on clinical and toxicological data is replaced by a demonstration of traditional use of the product for 30 years, 15 of which within the EU. The applicant only has to provide data on product quality. Theoretically, the regulations sound easy to fulfil and straightforward. In practice, however, they are not, which will be discussed below.

The date of 30th of April 2011 marks the end of the transition period, the day when herbal medicinal products or herbal products sold with a medicinal indication must be registered to be allowed on the market.

Is the petition therefore right and all non-registered herbal products will immediately be banned?



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Clearly no: the THMPD only and exclusively related to the drug sector, but does not regulate the food sector. Products which are now legally on the market as food (including food supplements) will still be allowed on the 1st of May 2011 – the problems with the process of Health Claim approvals by the EFSA notwithstanding.

Will peppermint tea be banned as there is a community monograph for peppermint leaves?

Again clearly no. Peppermint tea will only be regarded as an herbal medicinal product when it comes with a medicinal indication. According to the monograph the wording “*Traditional herbal medicinal product for the symptomatic relief of digestive disorders such as dyspepsia and flatulence*“ is foreseen and requires registration. If no such indication is given and peppermint tea is marketed as an herbal infusion the product does not fall under the scope of the THMPD, and a registration is not required. The decision what will be acceptable and what will not be will come down to a case by case review of the plants used in a product and the claims made for the preparation.

What will happen to not yet concluded registrations?

Nothing. As a matter of fact, drugs including registered herbal medicinal products can only be marketed once the application is granted. Consequently, the products in the process of registration cannot currently be on the market in the category of a drug, and consequently the end of the transition time will have no economic impact on the products in the course of registration.

Despite these re-assuring thoughts not all is well.

There are in fact tremendous problems with the current situation and the current wording of the THMPD. These problems must be seen in the context of the Health Claim Directive and the drafting of opinions for health claims of “botanicals” to be implemented by the EU commission. Quite obviously, this procedure will lead to the denial of health claims for at least 90 % of all herbal preparations currently sold as food supplements – which is equivalent to a de facto ban of the vast majority of herbal preparations in Europe. The petition is therefore quite right with respect to the result, but not totally with respect to the legislation it addresses. The procedure applied by the EFSA was neither transparent nor does it use acceptable scientific standards. In fact the conditions to get approval for a claim such as “peppermint is good for digestion” would hardly stand a chance to be accepted, as EFSA rules include the demonstration of the benefit by clinical trials performed in healthy people (which is already practically impossible to provide), whereas the registration as a traditional herbal medicinal product would not even ask for clinical data!

As a consequence, most herbal preparations currently sold as food supplements will lose their health claims in the near future, and thus the chances to be marketed.

Why haven't the supplements used the simplified registration? – Because in most cases they can't!

The THMPD has been created as a means to simplify the transformation of food supplements into controlled medicinal products. However, the process does not work, as can be seen in the very low registration figures in the member states. The reasons are obvious:

1. The current rules exclude a large part of products due to the “15-years within the EU” rule

Although technically many products have been “around” for a long time, the proof is frequently difficult to give. In many cases there is no possibility to demonstrate a continuous use within the EU, although at some time the use may have been quite extensive. As tax rules do not foresee storage of backlogs for more than 10 years, much valuable information such as trade invoices was already lost at the time when the legislation was passed. Other products have been extensively used, but do not reach the minimum duration. They are therefore not eligible as traditional herbal medicinal products. They can, however, frequently not be updated to the level of bibliographic licensing due to the lack of clinical data.

In the case of Ayurvedic preparations the time frame of 15 years within the EU can most likely be met, but the conditions for the proof of continuous use will probably be difficult to fulfil. In addition, the interpretation of this rule is not harmonized throughout the EU.

The EUAA therefore suggests the formulation of clearer rules, and eventually a shortening of the 30 years of use to 20 years, 10 of which within the EU.

2. The procedure excluded a large part of products due to the “only herbals rule”

THMPD is by definition “plants only”. This does, however, not reflect the realities, where minerals are often present as actives and thus not as “ancillary agents” as allowed by the THMPD. Many products also contain natural plant constituents such as thymol or menthol, or actives of animal origin such as honey or propolis. Ghee butter (clarified butter) or cowry (calcium carbonate from shells) are typical and essential constituents of Ayurvedic preparations, but the presence of such constituents would effectively close the door to registration.

Example: Whereas it was formerly possible to register a traditional non-herbal medicinal product according to §109a of the German drug legislation, this approach is now effectively barred. Example: A product containing silica gel and traditionally used for many decades for the structural improvement of hair and nails could no longer be registered under drug status.

As the rule of 30 years was created to ensure the safe use, the same safety would necessarily apply to non-herbal constituents used over the same period

of time. There is no reason to believe that ghee butter or honey should be more dangerous than any herbal constituent.

The EUAA therefore suggests that the wording “traditional herbal medicinal product” be changed to “traditional medicinal product”, which would effectively solve the problem without changing the overall safety situation.

3. The interpretation of the choice of indications is too restrictive

The choice of indication is often hampered by the eligibility of claims which do not require medical intervention. In fact drugs are addressing populations with given symptoms, and although the underlying disease may usually have to be confirmed by a medical diagnosis, the interpretation of which indication is still eligible shows tremendous differences throughout the member states. E.g., a patient suffering from diagnosed mild prostate hyperplasia may take use pumpkin seeds without having to return to the physician for every new box – the diagnosis will not change. Consequently, some member states would allow a pumpkin seed preparation as traditional herbal medicinal product, whereas others take the position that prostate hyperplasia is not an OTC indication.

4. The registration procedure is too expensive and too time-consuming

Registration of a traditional herbal medicinal product requires the submission of a full quality dossier. The EUAA endorses the importance of controlled product quality as a major pillar of consumer protection. The devil, however, lies in the details.

Even in the best of cases the development of the registration dossier a simple herbal mono-preparation (plant powder in single dose form) will cause costs of minimum 200,000 € - most of these costs are due to the development of analytical and manufacturing methods, their validation and product stability testing. As a product can technically not be marketed with a shelf-life of less than 2 years, the registration process will under ideal conditions take a minimum of three years – three years during which there will be no return of investment. In addition, the same effort must be made of every single product and every single galenical form. Small enterprises which are currently selling in small batches as food supplements will not be able to invest this money – and as a consequence it can be expected that the products will in the future increasingly be sold via uncontrollable internet channels, which would counteract the idea of product quality.

Ayurvedic and Chinese herbal medicinal remedies are typically multiherb combinations. Every additional constituent adds to the burden of proof of quality, especially on the level of stability testing. Already with three herbs the quantification of every single constituent becomes a challenge. Typical developmental costs for a three-herb-combination can easily reach 300-500,000 €.

The more constituents the less likely can the quantification of every single constituent be made. Actual guidelines allow for using a surrogate marker in such cases, but the use must be justified. This justification may well become very expensive by demonstrating that an analytical solution is not possible (scientifically an impossibility, but still required).

This brings us to the major question: Markers for stability testing of traditional herbal medicinal products are just that: markers, without a clear relation with efficacy. If, however, there is no relation between marker and efficacy, and the use of a surrogate marker is possible upon justification, why should it not generally be possible to select a single surrogate marker for combination products without the need of a justification?

The EUAA suggests that the quality of herbal medicinal products be tested on the level of the herbal substance (absence of contaminants, if available tests and quantifications according to pharmacopeia monographs). On the level of the drug product, however, physical tests, the identification of the constituents (e.g., by TLC) and the assessment of a surrogate marker should be sufficient, and at the same time keep up a very high level of quality.

Suggestions

- The EUAA suggests a shortening of the 30 years of traditional use to 20 years, 10 of which within the EU.
- The EUAA suggests removing the word “herbal” from the regulations of traditional herbal medicinal products in order to allow traditional non-herbal constituents to be registered as drug preparations with controlled quality.
- The EUAA endorses the current discussion that OTC indications should also include chronic diseases once diagnosed by a physician, which do not require constant medical surveillance.
- In order to really simplify registration and lessen the economic burden of developing the registration dossier the EUAA suggests simplifications on the level of the stability testing of traditional medicinal products, especially for combination products: a surrogate marker should generally be sufficient, especially when the quality of the single herbs has already been demonstrated.