



---

## **Impressions from the EMEA session on implementing lists of traditional and well-established herbs**

(from Dr. Matthias Schmidt, representing EFCAM and ANME e.V.)

London, November 22, 2005

As expected, the meeting did not start in time, but was 30 minutes late. Unfortunately I had to leave early (at 6.30 p.m.), and I was not able to listen to the suggestions of about half a dozen organisations (mostly the industrial associations) and participate in the discussion. However, I was able to deliver a statement just in time before leaving. The statement corresponded to what was presented to the EFCAM members beforehand, and was in line with some other organisations.

The session was opened by some introductory remarks of the chairman, Dr. Keller, who explained what had happened so far. To give the short version: EMEA is still at the beginning of the process, and nothing substantial has been done on creating lists of traditional or well-established herbs/preparations. EMEA has now been actively pursuing its goals for one year, and was mostly concerned with the implementation of the new EU regulations. There were two meetings in 2004, and 6 in 2005. There will also be six in 2006, but extended to 3-day-workshops for the creation of the monographs necessary to include the herbs into the lists. The results of the past meetings are the draft papers on traditional herbs (EMEA/HMPC/182320/2005) and well-established herbs (EMEA/HMPC/182352/2005), which can be found on the website of the EMEA.

As yet there are only 5 draft monographs which are mentioned on the webpage of the EMEA. There are still unsolved questions regarding the scope of the data needed for the introduction of a plant in a list. E.g., the requirements for genotoxicity study material are still under debate, which – in my opinion – is a bad sign. It sounds as if the requirements are set rather high, even with herbs that have been around for a long time.

Another open point is the method how traditional use can be established: which sources can be used, what kind of material is needed to provide reliable information on long-standing use in a certain indication. My personal experience in this field tells me that it will be very difficult to provide this kind of information if only scientifically sound journals are to be used.

EMEA plans the creation of 40-50 monographs in the first step, with plants having an ESCOP monograph being treated with priority. A major problem seems to be the funding and the sourcing of the literature. EMEA has no budget for literature and specifically asks for support.

Being in possession of a wealth of literature for various plants myself, I offered Dr. Keller our support in my statement, provided he tells us what he needs. This offer might bring EFCAM into a better position for being noticed on the level of the Herbal Medicinal Working Party, and – in case the EMEA asks us for help, also allows us to provide support material not usually found in MedLine. For the opinion forming process, this might be crucial.

Most organisations present in the meeting had no suggestions for the priorities on the list. Some promised an input within the next 10 days. The GA (Society for Medicinal Plant Research), presented by Prof. Rudi Bauer, had submitted a list, which was, however, not disclosed to the auditorium. The GA suggested the creation of a third category next to traditional and well-established plants: Special extracts. This is in the interest of a few companies, namely Schwabe and Bionorica. Personally, I do not believe this idea will become reality, as it might be extremely difficult to draw the line which preparation would have to be regarded as “special”, with every extraction company having their own special way of extract production.

As I did in my statement, the GA pointed to the fact that a given plant might have to be included in both lists, or in the same list with various indications. Otherwise the GA is in favour of putting all plants with an ESCOP monograph on the well-established list.

The interest of the EHGA (European Herb Growers Association), presented by Prof. Carlo Sessa, was the quality of the herbal raw material. The EHGA participated in the creation of the WHO guideline on Good Agricultural and Collection Practice (GACP). As GACP was only recently implemented in European regulations, quality and traceability will be a major issue in the monographs, traditional as well as well-established. According to Dr. Keller, this is also applicable to homeopathic and anthroposophic herbal raw materials, as well as TCM. In all cases, the traceability and quality of the raw material will have to be provided.

The statement of Michael McIntyre from the EHPA was quite interesting. He was concerned that different ways of producing herbal preparations might not be adequately represented in the monographs. As an example, he mentioned that in the UK not only valerian teas, but also tinctures have been traditionally used ever since. In addition, McIntyre pointed out that small companies might not be able to afford the toxicology testing obviously required in the process of listing a plant. In a company producing a range of 50 herbal products, the costs easily amount to 5 million EUR and more, which is more than most companies could afford. High levels of toxicological requirements might thus lead to a tremendous loss of preparations on the market. Personally I believe McIntyre has a point here.

My own statement covered the offer to produce draft monographs for Traditional Chinese Medicine, as suggested by Mr. Zhu. It also transported the concerns regarding the status of herbs not included into a list as a consequence of the capacity problem on the level of the EMEA. I also repeated the suggestion of the GA regarding the listing of plants on both lists according to indication and evidence provided.

**In conclusion**, I had the impression that Dr. Keller would very much appreciate if draft monographs were provided by the interested parties, and submitted including the relevant literature. Such draft monograph proposals would of course have to be evaluated by the EMEA, but for them it would still be much easier to move forward.

My suggestions are as follows:

EFCAM should repeat the offer of support with literature to the EMEA in written form within the next days. In this letter, the EFCAM might also offer the assistance in producing draft monographs. With the background that the process of list creation in fact also covers the fields of antroposophy and homeopathy, EFCAM can and should also submit a list of suggestions for the inclusion of plants or preparations into one or both of the lists.

All EFCAM members are called to give some thought to the questions which might be the kind of preparation absolutely indispensable in therapy. Even though the contingency of 40-50 monographs is already overstuffed with the 80-90 existing ESCOP-monographs (plus the WHO monographs), it is important to at least raise ones finger at this point.