



Traditional Herbal Medicine – „traditional use“

Statement from ANME e.V. relative to the problems occurring by the practical implementation of the directive 2001/83/EC, i.e. the directive 2004/24/EC (herbal preparations) as a body of rules enabling a simplified registration of natural products with long term tradition.

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1. The request of the responsible authorities to issue further toxicological tests can be estimated to reach costs of approx. 150.000 up to 200.000 euros per product. The “simplified registration” requires the issue of a quality file (further costs?)
2. The requirements towards traditional drugs are not defined. This leads in practice to a permanent re-interpretation. What do traditional utilisation, regular use, relevant quantity mean?
3. It is unclear whether the toxicological evidence applies to the dispensing or to each individual plant.
4. Only a small amount of EU-monographs will be available until 2011. Other previously available monographs are ignored on the part of the HMPC (EMA).
5. The unsettled situation between the EU-commission and the HMPC (EMA) slows down the procedure i.e. affects it negatively and is at the expense of herbal medicines. A positive example in that regard is the attitude of the EFSA as an accompanying applicant for food additives and should be preferred to the restrictive attitude of the HMPC.
6. The non European traditional medicines (i.e. Asiatic medicine) have got little chance. Professional organisations should be called upon as experts for such medicines, to issue indications in accordance to the traditional registration.
7. As yet the producers report enormous difficulties to cover all requirements, see the 30 years utilisation (i.e. documentation and sales data should be stored only 5 to 10 years according to commercial laws)
8. It is almost impossible for small companies to cover the documentation requirements concerning the utilisation of traditional medicines and possibly also food additives (Foodstuffs)

9. Because of the previous practice, a modification has already emerged by the well tried traditional medicines. Can we still speak about “traditional”? Furthermore the required change processes are taking place at variable speeds in the different EU Member States

10. A product differentiation into “well-established” and “traditional use” is impossible. A reference considering the registration should be redefined.

11. There is no possibility so far for a simplified registration regarding components of animal origin.

12. The regulatory authority expects as a sort of “test case” an application for simplified registration to be submitted, at applicant’s costs – despite an uncertain issue.

13. It is fundamental to keep the consumers safety in mind. However, the restrictions on harmless products deteriorate the EU-citizens’ health.

14. The foundation of regulatory decisions should not be affected by speculations or excessive fear but should rely on knowledge and be decided with the agreement of all parties concerned.

15. The possible abandonment of pre-clinical efficaciousness tests in case a medicine is proved to be inoffensive reverse to our point of view the causer principle: Not the noxiousness but the innocuousness has to be proved.

16. The financial and bureaucratic hurdles for a thorough research as meant by the CAM have been tremendously increased. A further development of traditional medicines is consequently hindered.

17. The tremendous conditions imposed by the introduction of new medicines (herbal and/or other) to the producer could lead to questionable avoidance strategies and are contrary to consumers’ benefit.

Annex:

18. A new hurdle has been in set in October to the herbal medicines by the German BfArM. According to Point 15 and with immediate effect, have all herbal medicines to prove that they are not damaging the genetic material (keyword “genotoxicity”). ANME e.V. sees in this requirement the beginning of a further cutback of the herbal drugs range in Germany with consequences in Europe and therefore insists expressly that this requirement be revised or rather withdrawn.