EUROPEAN COMMITTEE FOR HOMEOPATHY

Contribution to discussion at homeopathic workshop at EMEA on 27th October 2006

REPRESENTATION

- **Representing 12,000 medical doctors with education and training in homeopathy as a method**
- **Joining 38 homeopathic doctors' associations in 23 European countries**

THERAPEUTICS

- Homeopathy has a highly individualized character

- As a logical consequence, in the search for the most suitable homeopathic medicinal product for the individual patient, homeopathic doctors should have access to a large range of single homeopathic medicinal products (about 3,000 at present)

OBJECTIVE OF EU DIRECTIVE 92/73

(recital)

"Whereas, despite considerable differences in the status of alternative medicines in the Member States, patients should be allowed access to the medicinal products of their choice, provided all precautions are taken to ensure the quality and safety of the said products"

PRESENT SITUATION (14 YEARS LATER)

- National interpretation and implementation of the EU directives 2001/83 and 2004/27 vary from country to country -> some medicines have disappeared from the market in some countries, whereas in other countries they are still available

- Homeopathic industrial manufacturers register only those products that are economically feasible (e.g. in the Netherlands 600 out of a total of 3,000)

- There are many “kinds” of Belladonna on the market, but medicines V, W, X, Y and Z are unavailable, because not registered

PRESENT SITUATION (14 YEARS LATER)

- Homeopathic medicinal products whose raw material is of biological origin disappear from the market, because they must fulfill all kinds of strict safety requirements even if these medicinal products are only used in high potencies that are safe by dilution itself (no molecules -> no prions/viruses)
- The development of homeopathy is seriously hampered because new medicines cannot be registered
- About 20 % of the total number of patients seeking homeopathic treatment cannot receive adequate treatment

PRESENT SITUATION (14 YEARS LATER)

Conclusion

The limited availability of homeopathic medicinal products restricts adequate patient care, which assumedly has never been the intention of the authorities who originally established the Directive on homeopathic medicinal products

POSSIBLE SOLUTION 1

Central registration at EMEA
to overcome current
national differences in regulation

POSSIBLE SOLUTION 2

Adoption of Swissmedic model

It has 2 simplified procedures:

- a simple reporting procedure (‘Meldeverfahren’) for a large number of listed HMPs whose dossiers need not be submitted for registration but only available with the manufacturer (e.g. Belladonna above 4D, nosodes such as Carcinosinum or Medorrhinum above 12C)
- a simplified registration procedure that requires a dossier to be submitted in case of non-listed HMPs, low-potency HMPs, parenterally applied HMPs, HMPs of human/animal origin below 12C or 24D/X

Strikingly, this model allows even a simplified registration of injectables and mother tinctures!

Could this model, approved by Swiss experts for its safety and quality, also be a workable model for the EU?

POSSIBLE SOLUTION 3

- The Swiss one-thousand rule = homeopathic medicines produced in low quantities, i.e. lower than 1,000 samples do not need a registration

[This rule also exists in Germany, but has been restricted to homeopathic medicines of mineral and botanical origin]

POSSIBLE SOLUTION 4

- Safeguarding magistral and officinal formula prescription

  Starting materials, homeopathic stocks and first potencies should be available for specialized pharmacies to make homeopathic magistral and officinal preparations for those medicines that can never be produced on an economically sound basis and an industrial scale.

  Quality may be assured by requirement of GMP-licensed manufacturers and analytical certificate

  These starting materials, homeopathic stocks and first potencies should NOT be designated as homeopathic medicinal products.

POSSIBLE SOLUTIONS

Or: any combination of these solutions

CONCLUSION

Would EMEA be willing to play a role in ensuring that European patients have access to the medicinal products of their choice, as was originally intended by EU Directive 92/73?