Homeopathic Medicinal Products - Perspectives in Europe

BfArM conference in Bonn, June 18th 2007

The concerns of homeopathy practitioners in relation to Homeopathic Medicines

A presentation on behalf of:

- **VKHD** - German national professional association of Heilpraktiker homeopaths
- **AEHA** - alliance of BKHD, DZVhÄ, VKHD
- **ECCH** - European Council for Classical Homeopathy
- **ECH -** European Committee for Homeopathy

Practitioners' cooperation on a national level AEHA, Germany

"Anwenderbündnis zum Erhalt homöopathischer Arzneimittel"
"Users alliance for the availability of homeopathic remedies"
AEHA is an alliance of VKHD, BKHD, DZVhÄ, organisations representing German homeopathic doctors and Heilpraktiker homeopaths

The alliance shares a main concern:

The full availability of all homeopathic medicines in high quality in order to effectively treat patients

Cooperation on a European level

- **ECCH** - (European Council for Classical Homeopathy), a council of 27 national professional associations of homeopaths in 23 countries. German member = VKHD
- **ECH** - (European Committee for Homeopathy), an umbrella of 38 homeopathic doctors' associations in 24 European countries, representing all homeopathic doctors in Europe. German Member = DZVhÄ
- **ECCH - ECH** cooperation is taking place
  → joint position paper on HMPs to be published soon
- **ECCH & ECH** are corresponding members of **ECHAMP**
- **ECCH & ECH have responded to recent consultations on HMPs of HMPWG and WHO**

ECCH and ECH share the same concern –
full availability and high quality of all HMPs
in order to effectively treat patients

Cooperation in the area of CAM

Germany - Heilpraktiker-Associations

European - ANME, EFCAM, IVAA, ECPM

- **Other CAM professionals use HMPs**
- **There are availability problems with other groups of CAM Medicinal Products e.g Anthroposophical, Herbal, etc.**

Bottom Line: *public and professional freedom of choice of therapy is threatened by the lack of availability of medicines*

In CAM regulatory and pharmaceutical affairs, we recommend national regulators involve representatives of stakeholder groups

- doctors and practitioners (relevant associations)
- manufacturers (relevant associations)
- patients (relevant associations)

e.g. as represented in today's invitations by the BfArM,

Stakeholder involvement and transparency should be an essential part of "good regulatory procedures" in all countries.

"Quality" is the keyword for practitioners and patients

To be able to provide high quality patient treatment, homeopathy practitioners need:

- a good education & training followed by continual professional development
- effective professional regulation of practice based on ethical and safety standards, bounds of competence etc., ...
- ***full availability of all homeopathic medicines in high quality to effectively prescribe for patients***

Safety is a product of production quality for homeopathic medicines

In our understanding:

- Homeopathic medicines have been used safely for 200 years
- There are no known unsafe product records
- The current safety discussions for HMPs reflect safety concerns in other pharmaceutical categories
- Potentisation alone using homeopathic GMP renders ALL high potency HMPs safe by dilution alone
- ***Safety should always and only refer to the finished product placed on the market.***

Availability is a Quality Need for Effective Homeopathic Practice

In our understanding and experience:

From the law of similars, an indicated homeopathic medicine cannot be replaced by any other

Restricted availability results in decreased precision in individualised homeopathic treatment

Lack of the full range of HMPs means

→ some patients cannot be treated in the best way
→ some patients cannot be treated at all
→ a growing black market of illegally made medicines or foreign imports, particularly of nosodes

Our Quality Concerns, an Overview

- loss of important nosodes, due to excessive regulatory requirements esp. on raw materials
  — in Germany e.g. *Carc*., *Med*., *Lues*.
- denaturising treatment of certain raw materials, even for high potencies without any distinction
- loss of seldom used remedies, due to excessive paperwork and costs
  — resulting loss in Germany, Netherlands, etc.
- difficulties for registering new remedies, esp. if no previous pharmaceutical use
- remedies having to be imported from other countries

Quality Needs for homeopathic medicines from the practitioner's perspective
from the present position paper of ECH & ECCH

Sourcing and production of homeopathic medicines:

- raw material used for the production of a homeopathic medicinal product should match the source and state of the raw material used in the original proving(s) as closely as possible.
- proper and careful application of agreed production methods (GMP) appropriate for homeopathic medicinal products.
- refraining from any treatment or influence, which is not part of the agreed production methods for homeopathic medicinal products.

The Need for Nosodes in Homeopathy

In 2005 the VKHD carried out a survey

VKHD members and readers of “Homöopathie-Zeitschrift” (mostly single remedy prescribers, no strict selection).

Results published 2006 in “Homöopathie-Zeitschrift” showed:

- Nosodes are needed in 33% of all successful homeopathic treatments of chronic diseases, with no significant difference in age groups
- Nosodes are considered indispensable in all kinds of chronic conditions e.g. chronic recurrent infections, neuro-dermatitis, asthma, ADHS, urogenital diseases, psychological disorders and many others ...

The Need for Nosodes in Homeopathy (2)

- homeopaths also prescribe nosodes for acute diseases: frequently (17%), occasionally (42%) or rarely (34%).
- prescription is mostly based on homeopathic, not isopathic, principles
- only 2,4% use potencies below C6/D12
- ***Conclusion - Nosodes are indispensable in the treatment of chronic and acute diseases***

Most homeopaths use nosodes in high potencies i.e.(C 30, C200, C1000, C10.000) — and with infrequent dosage and application

Sales figures of nosodes are not representative of the degree of use

Nosodes, availability problems — survey 2005 & other sources

- 78% of all reported availability problems concerned the “classical five” *Carc.** (diff. kinds, 40.58%), *Tub.* (diff. kinds, 17.39%), *Med.** (14.01%), *Lues.** (5.23%), *Psor.* (0,48%)
  * still unavailable
- 22% of all reported availability problems concerned “seldom used” and vaccination nosodes
- both “classical” and “seldom used” nosodes are needed
- the German company *Staufen Pharma* has lost 90% of it’s production range in recent years.

Nosodes, excessive safety requirements are the problem

- application of blood donor requirements to donors
- required amount of testing material very difficult to obtain, required testing with guinea pigs etc.
- freedom from pathogenic agents of source material
- lack of differentiation of the needs for low and for high potencies

Nosodes, quality problems

- high potency $\rightarrow$ high “grade of similarity” is needed (see G.H.G. Jahr, Vithoulkas, diff. textbooks)
- irreversible protein changes occur above 40°C
- raw materials are now heated to 133°C, in Germany (prior to 2001 it was 120°C)
- ***for high potencies, the denaturising treatment of source materials is a quality problem***

Nosodes and animal source homeopathic medicines, Safety by dilution

- For low potencies: the viral load of raw materials has to be reduced
- For high potencies: safety alone by dilution is possible
- Relevant factors:
  (1) minimal infectious dose
  (2) maximum concentration of potentially harmful agent
  (3) daily intake & safety margins

Nosodes and animal source homeopathic medicines, Safety by dilution(2)

- safety in a worst case scenario: Avogadro number 10^{-23} $\rightarrow$ D23 / C12 and above
- minimal infectious dose & concentration finished product $\rightarrow$ lower potencies possible
- rational risk assessment of finished product
  $\rightarrow$ choose a “safety model” according to lowest potency the manufacturer wants to bring onto the market

<u>In summary:</u> our one concern is maintaining the full availability of all homeopathic medicines, including all nosodes, in high quality in order to effectively treat patients.

In order to achieve this we wish to remain *'in dialogue'* with all relevant authorities and the manufacturers concerned._

Thank you for your attention