COMMON RESOLUTION

Signed by associations of patients, practitioners and manufacturers
in the field of non-conventional medicinal products.

Brussels 2002

Resolution to the institutions of the European Union and the national medicines authorities of all EU Member States on the proposed revision of all EU pharmaceutical legislation (Directive 2001/83/EC on medicinal products for human use, Directive 2001/82/EC on veterinary medicinal products) especially with respect to the non-conventional medicinal products in general and the revision of the legal situation of the homeopathic medicinal products in particular.

The signed associations,

A. whereas an increasing number of consumers, patients and health care practitioners in all Member States are using non-conventional medicines;

B. whereas the view is increasingly widely held that different methods of treatment and different approaches to health and illness can be used to complement each other;

C. whereas between one fifth and one quarter of the citizens of the European Union make use of homeopathic and anthroposophic medicinal products and whereas such products account for more than one percent of the turnover and more than three percent in number of sales of pharmaceutical products in the European Union;

D. whereas it is important to ensure that patients have the broadest possible choice of treatment, guaranteeing them the maximum level of safety and the most accurate and correct information possible on the quality, effectiveness, safety and possible risks of homeopathic and anthroposophic medicinal products;

E. whereas the nature of these medicinal products together with their long tradition of harmless use guarantees that there is no significant risk for public health whether from treatment of human or animal health problems;

F. whereas eight years after the publication of the Directives 92/73/EEC and 92/74/EEC the Internal Market for homeopathic and anthroposophic medicinal products is far from being finalised, and whereas these products are excluded from the mutual recognition procedure and almost all EU-Member States do not accept registrations or market authorisations of homeopathic and anthroposophic medicinal products which were granted by authorities of another Member State;

G. whereas the implementation of the Directives 92/73/EEC and 92/74/EEC was different from Member State to Member State and it becomes more and more clear in the everyday experience of practitioners and manufacturers there is a situation of serious disharmony in the European Union in this field;

H. whereas restrictive and unclear paragraphs in the Directives cause a severe problem of availability of homeopathic and anthroposophic medicinal products

to consumers on the one hand and an important restriction for homeopathic and anthroposophic practitioners prescribing these medicinal products on the other;

I. whereas registration and authorisation costs and fees as well as the workload are not adapted to the large range and the quite low turnover of homeopathic and anthroposophic medicinal products, especially for products that are less frequently prescribed, although they are necessary for patients with specific diseases;

J. whereas recent health economic evaluations of homeopathic and anthroposophic medicinal products suggest a positive cost-risk-benefit profile;

call on the responsible institutions on a European and national level, i.e. the European Commission, the European Parliament and the Council of Ministers on the one hand, and the National Health Ministries and Medicines Agencies on the other, to respond to the following resolution:

A. For Non-Conventional Medicinal Products in general

1. As regard to appropriate directives, guidelines and procedures enabling a European approach,

a revision of the existing legislation and regulatory framework, both EU and national, must cover non-conventional medicinal products and has to take into account the peculiarities of these products and their low risk / low cost benefits for public health. The framework should provide pragmatic solutions for the appropriate assessment of quality, effectiveness and safety of these medicinal products, based on their well-known nature and their long tradition of use in the European Union.

As a first step binding rules for a specific mutual recognition system of registration and marketing authorisation of non-conventional medicinal products should be established in all Member States in order to proceed more effectively towards harmonisation. However, given the difficulties of mutual recognition, we would advise a move towards a central registration and market authorisation system on a European level. This would further help to establish the balance between cost and benefit for authorities and manufactures.

2. As regard to appropriate expertise in the area of non-conventional medicinal products,

the revised EU pharmaceutical legislation should provide for a specific committee and subcommittees of expertise dealing with non-conventional medicinal products to be created by the European Commission to parallel the role and activity of the Committee for Proprietary Medicinal Products (CPMP).

We as professional associations of non-conventional practitioners, consumers and manufacturers ask to be consulted and involved as our knowhow and expertise in the field is broadly recognised. We urgently ask that experts familiar with non- conventional medicine should be involved in the development of specific rules, guidelines and notices to applicants as well as in the development of monographs for a "European Homeopathic Pharmacopoeia".

3. As regard to clear statements and communication,

clear and harmonised definitions of key words in directives, rules, procedures and guidelines are urgently needed in order to avoid divergent interpretations by the different legislative and regulatory authorities concerned in the Member States. Consumers / patients and practitioners demand objective, clear and accurate information on labelling and in leaflets to ensure appropriate use of the product.

In this respect disclaimers are unacceptable.
In order to avoid possible confusion for the consumers and to promote clear communication we also suggest the additional use of invented names for combination products so that they can be easily identified.

B. For Homeopathic and Anthroposophic Medicinal Products in particular

1. As regard to the significance of homeopathic and anthroposophic medicinal products in the society of tomorrow,

homeopathic and anthroposophic treatment and the associated medicinal products should be accessible as a matter of freedom of choice for all patients irrespective of a patient's age, gender or condition. The subscribers underline that the freedom of choice for the patient as well as for the practitioner must be respected.

It is essential that the availability of all existing and future single homeopathic remedies is maintained for the potential benefit of all Europe's citizens and their animals. Legislation and registration procedures should not cause restrictions to the continued use of existing or the development of new homeopathic and anthroposophic medicinal products. This should also be respected as regarding other pharmaceutical forms such as injections, suppositories and eye drops. Although the quality and safety of these galenic forms are guaranteed by GMP (Good Manufacturing Practice) and Pharmacopoeia Monographs, they are excluded from the simplified registration procedure according to the homeopathy Directives.

Proper national and European budgets for the financing of large research projects should be established, in particular in order to demonstrate the cost-effectiveness of homeopathic and anthroposophic medicinal products in every-day healthcare and to recognise their potentially important role in an evolved integrated healthcare system in the European Union.

2. As regard to the significance of veterinary homeopathic and anthroposophic medicinal products,

the simplified registration procedure should also be accessible for products intended to be administered for food-producing animals. The safety and quality of these products is perfectly guaranteed by the regulation on the allowed maximum residue limit (regulation No. 2377/90), where homeopathic medicinal products from a certain degree of dilution are estimated to be without risk for the consumer. Further, organic agriculture is depending very much on the availability of homeopathic medicinal products for their animals.

This RESOLUTION is fully in line with the report submitted by the Commission on July 14th, 1997 on the application of Directives 92/73/EEC and 92/74/EEC on homeopathic medicinal products (COM(97) 0362 C4-0484/97), and with the European Parliament's resolution on the Commission report to the European Parliament and the Council on the application of Directives 92/73/EEC and 92/74/EEC on homeopathic medicinal products (Com(97)0362 C4-0484/97) adopted on November 5th, 1998.

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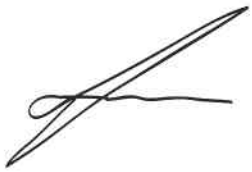

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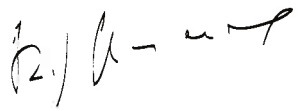

ECVH

European Coalition on Veterinary Homeopathy

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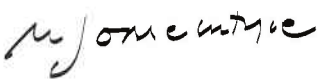

IAVH

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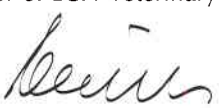

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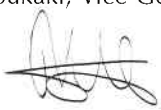

IVAA

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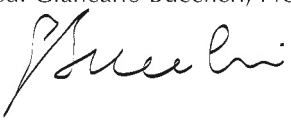

Frank Mulder, MD, Member of the Council