Homeopathic and Anthroposophic Medicinal Products

A call to action

Legislative term 2009-2014
of the European Parliament
and the European Commission

ECHAMP

A call to action

Whereas,

- over 100 million citizens use homeopathy and/or anthroposophic medicine for their health care in the European Union
- homeopathic and anthroposophic medicines are safe, effective and cost-effective and manufactured to high quality standards
- homeopathy and anthroposophic medicine meet many of the goals of the European Commission's strategy for improving health in the EU
- patients, doctors and practitioners are being deprived of the medicines they need by an increasingly unharmonised EU legal and regulatory framework
- the European Commission first recognised the limitations of the current legislation in 1997[1]
- the European Parliament called for amendments to the existing legislation in 1998[2]
- a European Court of Justice ruling in 2007[3] recognises the need for regular review of the legislation in this field
- the EU institutions have a legal and political obligation to ensure that legislation is fit for its purpose,

ECHAMP calls on the European decision makers to:

- recognise the importance of homeopathy and anthroposophic medicine and the need to integrate these European therapeutic traditions in EU health policy and programmes
- create a harmonised and workable legal and regulatory environment for homeopathic and anthroposophic medicinal products across the EU in order to comply with the legitimate demand of the citizens, prescribers and patients for these products
- develop and support proposals to revise the relevant articles in Directive 2001/83/EC (via co-decision) and Directive 2003/63/EC (via comitology) as well as the creation of specific provisions applicable to anthroposophic medicinal products also in Directive 2001/83/EC
- urge the Member States to set up a common and affordable programme to bring the products that have already been on the market for many years into an appropriate regulatory framework, proportionate to the low risk of these safe, well-known and well-established products, maintaining fees at an acceptable level.

[1] *European Commission, Final report on the application of Directives 92/73/EEC and 92/74/EEC regarding Homeopathic Pharmaceutical Products, COM(97)362 final*
[2] *European Parliament, Report on Commission report COM(97)362 final, A4-0378/98*
[3] *Case C-84/06, Netherlands v Antroposana and others [2007] ECR I-07609, paragraph 40, and paragraph 63 of the Opinion of Advocate General Bot*

Established European traditions

> '…the existing Directives need to be amended .. (to) ensure the free movement of homeopathic medicinal products, and ..(to) take account of the peculiar nature of homeopathic medicinal products'
> European Parliament report A4-0378/98

Homeopathic and anthroposophic medicinal products have been safely on the market in Europe for decades; they are used today by more than 100 million Europeans. The industry for these products represents 1% of the European pharmaceutical market and 7% of the European non-prescription market.

The EU took a first initiative to harmonise legislation for these products in 1992 with the adoption of European Directive 92/73/EEC.[4] However the current EU legislative framework for homeopathic and anthroposophic medicinal products, rather than leading towards harmonisation, is severely inhibiting industry growth and development. Patients, doctors and practitioners are being deprived of the medicines they need.

There is an urgent need for further actions in this field to allow European citizens easy access to the medicinal products they need.

[4] *Council Directive 92/73/EEC of 22 September 1992 widening the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by Law, Regulation or Administrative Action relating to medicinal products and laying down additional provisions on homeopathic medicinal products*

Homeopathy and anthroposophic medicine - their contribution to European health care

Homeopathy and anthroposophic medicine have been widely used in Europe and other parts of the world for decades. In Europe, over 100 million citizens use these therapies for their health care, including both over-the-counter products and consultations with a doctor or practitioner.

Homeopathy and anthroposophic medicine are aimed at improving the level of health by mobilising a patient's own natural systems for fighting disease and maintaining health. Treatment is individualised and different people receive different treatments even if they suffer from the same disease. The individual approach meets a growing need for a more personalised way of healing. These medicines can also be used for self-treatment of common everyday ailments.

Homeopathy - an individualised treatment based on holistic assessment
Homeopathy is an effective method of healing in both acute and chronic conditions. A homeopathic assessment includes not only the patient's actual complaints and conventional diagnosis, but other elements, such as his or her constitution and the way he or she responds to physical, emotional and mental influences in life.

Homeopathy can be used by patients suffering from all kinds of diseases, including as a first option in certain medical conditions, and may offer long lasting to permanent cure for many ailments.

Anthroposophic medicine - a model for integrative medicine
Anthroposophic medicine is integrated into public health care in several EU countries and practised in university teaching hospitals, public hospitals, emergency care and clinics for special disorders. It builds on the well-established facts and methods of diagnosis and treatment in conventional medicine with a comprehensive and holistic analysis, leading to a highly individualised approach to treatment. It uses both ordinary medicines and special medicines produced according to specific pharmaceutical procedures. Some are prepared according to official homeopathic pharmacopoeias, and some are similar to herbal medicinal products.

- Approximately 45 000 physicians in the EU are trained in homeopathy
- Between 25 and 40% of general practitioners prescribe homeopathic medicines
- More than 30 000 doctors prescribe anthroposophic medicinal products; anthroposophic medicine is only practised by those with dual training as a physician and as an anthroposophic doctor

Quality, safety and efficacy

EU legislation relating to medicinal products, including homeopathic and anthroposophic medicinal products, ensures that all medicines are evaluated according to their quality, safety and efficacy for human or veterinary use. The quality, safety, efficacy and cost-effectiveness of homeopathic and anthroposophic medicinal products are all well-documented.[5]

Quality
The starting materials for homeopathic and anthroposophic medicinal products are mineral, plant (mainly fresh) and animal substances. Production and quality control of these products are carried out in accordance with international guidelines for Good Manufacturing Practice (GMP) and official pharmacopoeias.

Safety
Risks from homeopathic medicinal products are minimal in comparison with those of conventional medicine, because the concentration of active principles is very low compared with most conventional medicines.
The safety of both homeopathic and anthroposophic medicinal products is well-documented. The frequency of adverse reactions is very low and serious adverse reactions are very rarely reported.

Efficacy
The body of clinical evidence for the effectiveness and efficacy of homeopathy continues to accumulate.[6] Observational studies conducted in Germany and the UK consistently demonstrate real-world effectiveness of homeopathic treatment - that is significant decrease of disease severity and major improvements for quality of life.

In addition, research projects conducted to current scientific standards have been published in leading international medical journals over the last few decades. Several rigorous controlled clinical trials have shown homeopathy superior to placebo; others have shown it to have therapeutic effects similar to conventional treatments.

The effectiveness of anthroposophic medicine is based on ninety years of practice and experience in general practice and in clinical appliance.
In addition, research concludes that it is good, effective and safe.

Cost-effectiveness[5]

Homeopathic and anthroposophic medicines are normally less expensive than conventional prescription drugs, because they are generic, non-patented and non-patentable medicinal substances, produced at low cost. On the other hand, because homeopathic and anthroposophic doctors need to familiarise themselves with the patient's history, a longer consultation time is required than a conventional general practitioner consultation. The overall costs of treatment are therefore comparable to that of conventional treatment.

According to studies comparing the outcomes and costs of treatment by general practitioners who integrated homeopathy in their practice with those who did not, those who integrated homeopathy in their practice achieved better results for similar cost. Research into anthroposophic medicine indicates similar results.

However, from a long-term perspective these therapies will save money, because under proper treatment, not only do the patient's immediate complaints improve, but his or her susceptibility to disease decreases as there is a general improvement in health and thus less need for medical consultations.

[5] *See www.camdoc.eu and www.eiccam.eu for a bibliography and research references for each of these topics.*
[6] *Bornhöft G., The Scientific Status of Homeopathy, ECHAMP, May 2009*

Several research studies show that patients who were treated with homeopathy used fewer medications, had better health, fewer days off sick, fewer visits to medical specialists and less time in hospital than patients of conventional physicians. Moreover, there are no costs associated with complications due to adverse medication effects.

In other words, homeopathy and anthroposophic medicine have the potential to offer significant cost savings to public health bodies and to the wider economy.

Homeopathy and anthroposophic medicine - their place in EU health policy

> ‘Community health policy must take citizens' and patients' rights as a key starting point.’
>
> European Commission White Paper ‘Together for Health: A Strategic Approach for the EU 2008-2013’

The European Commission’s White Paper 'Together for Health: A Strategic Approach for the EU 2008-2013' focuses on principles and strategic themes for improving health in the EU. It emphasizes citizens' empowerment as a core value, saying that ‘healthcare is becoming increasingly patient-centred and individualised, with the patient becoming an active subject rather than a mere object of healthcare’ and that ‘Community health policy must take citizens' and patients' rights as a key starting point’.

Homeopathy and anthroposophic medicine fit clearly into the Commission’s strategy. Increasing numbers of European citizens show a definite preference for complementary medicine; homeopathic and anthroposophic treatment are both individualised; they are aimed at mobilising a patient’s own natural systems for fighting disease and maintaining health, and at avoiding long-term dependency on conventional drugs.

The Second Programme of Community Action in the Field of Health (2008-2013) promotes measures to improve patient safety through high-quality and safe health care. Homeopathy and anthroposophic medicine can play an essential role in this field because of their safety and effectiveness in the treatment of infectious diseases. It is recommended that the Community framework for safe, high quality and efficient health services, which is likely to be proposed by the Commission, should include reference to these complementary medicine approaches.

The legal and political framework for homeopathic and anthroposophic medicinal products

The first effort at harmonisation of homeopathic and homeopathically-produced anthroposophic medicinal products took place with the adoption of **Council Directive 92/73/EEC** in 1992, which widened the scope of Directives 65/65/EEC and 75/319/EEC in relation to medicinal products, laying down additional provisions on homeopathic medicinal products.

Its main goal was the harmonisation of national rules and administrative practices with respect to high quality homeopathically-produced medicinal products, in order to ensure their free circulation throughout the European Union and free access for patients to the medicinal products of their choice. From the beginning, and despite the good intentions expressed at the time, it was already clear that this piece of legislation contained too many flaws to attain its goal.

As early as 1997, the European Commission signalled in its Report[7] that the European rules on homeopathic medicinal products were not suited for meeting their target. In 1998, the European Parliament also emphasised the need for amendments.[8]

> '(…) a certain but not yet satisfying degree of harmonization has been attained in 1997'
> European Commission, COM(1997)362 final

> '…the existing Directives need to be amended .. (to) ensure the free movement of homeopathic medicinal products, and ..(to) take account of the peculiar nature of homeopathic medicinal products'
> European Parliament, A4-0378/98

[7] *European Commission, COM(97)362 final*
[8] *European Parliament, A4-0378/98*

Despite the efforts of some Member States and national competent authorities, the goal of free circulation of, and free access to high quality homeopathically-produced medicinal products has not yet been obtained in many Member States. Malfunctioning legal provisions have remained in place since they were first adopted. Both Member States and their national competent authorities struggle with the implementation of the rules. This leads to large differences between national rules with, in certain cases, Member States applying their own interpretations at the expense of the products.

Particularly but not exclusively problematic are:

- the varying national requirements for providing evidence on 'homeopathic use' of the stocks that are used to produce homeopathic medicinal products
- the special simplified registration procedure which lacks a scientific and sufficiently flexible and pragmatic approach to safety issues
- the absence of harmonised rules for those homeopathic medicinal products for which a marketing authorisation is required.

Without improving the current European rules, harmonisation - and thus free circulation and free access - cannot be attained. This was emphasised by the Advocate General and European Court of Justice in the *Antroposana case*[9] on anthroposophic medicinal products.

> 'In a field such as that which is before the Court, it is absolutely clear that the development of the Community rules at regular intervals is essential, and even unavoidable...'
> ECJ, Case C-84/06

Despite strong demand from European citizens, the European institutions have not (yet) displayed political commitment to bring about the necessary legal changes.

> 'To date … neither the Parliament nor the Council have reacted … The Commission, therefore, has not yet taken any decision...'
> Answer by the Commission to the written question by Hiltrud Breyer MEP to the Commission of 24 March 2009 on anthroposophic medicinal products (E-2257/09)

The deficits in the current European rules for homeopathic and anthroposophic medicinal products mean that they are unworkable. Where the EU institutions adopt legislation, they have a legal, political and moral obligation to ensure that it is fit for purpose. The current situation is unsustainable.

[9] *ECJ, Case C-84/06*

About ECHAMP

ECHAMP is the *European Coalition on Homeopathic and Anthroposophic Medicinal Products.* It represents the vast majority of the industry for homeopathic and anthroposophic medicinal products in Europe. ECHAMP's main aim is an appropriate legal and regulatory framework in order to achieve free and easy availability of these medicinal products in the European Union.

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