Homeopathic and Anthroposophic Medicinal Products in Europe

THE NEED FOR BETTER REGULATION

ECHAMP

'… the existing Directives … need to be amended in such a way that, firstly, application of the statutory and administrative provisions ensure the free movement of homeopathic medicinal products and, secondly, that when the additional rules are drawn up they take account of the peculiar nature of homeopathic medicinal products.'

A4-0378/98 European Parliament Report on the Commission report to the European Parliament and the Council on the application of Directives 92/73/EEC and 982/74/EEC on homeopathic medicinal products (COM(97)0362 - C4-0484/97)

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Introduction

Homeopathic and anthroposophic medicinal products are part of a long-standing European therapeutic tradition with a positive safety record established over many decades. The extensive range of products enjoys continuous growth in popularity with patients, doctors and practitioners. These medicinal products are used by over 100 million European citizens and represent about 7% of sales of non-prescription pharmaceutical products.

However, the current European regulatory framework, rather than leading towards free trade and European harmonisation, is inhibiting industry growth and development.

The future of the industry for homeopathic and anthroposophic medicinal products is under threat. The industry is severely restricted by overregulation, lack of capacity in the medicines agencies and lack of specific rules and harmonisation in the regulatory affairs environment. Patients, doctors and practitioners are being denied access to the medicines of their choice.

Homeopathic and anthroposophic medicinal products are inherently low-risk products. They are mostly derived from natural substances and differ from conventional pharmaceuticals in a number of ways. Fifteen years of experience show that the legal framework is not adequately tailored to the particular characteristics of these medicinal products.

There is an urgent need for better regulation of these medicinal products to preserve this important European industry and to foster development. A new initiative in this field would be in line with the EU Commission's declared intention to 'deregulate' in order to make Europe more competitive.

ECHAMP's vision is for all European citizens to have easy and equal access to safe, high quality and effective homeopathic and anthroposophic medicinal products. We call on the European Parliament to take political action to allow the 100 million European users of homeopathic and anthroposophic medicinal products harmonised, easy and safe access to the medicines of their choice.

100 million users

Three out of four Europeans know about homeopathy, and of these 29% use it for their health care.[1]

An established European industry with large growth potential[2]

Turnover (2005): € 1 771 million (consumer prices)
Average consumption per head of the population: € 4
% of European pharmaceutical market: 1%
% of European non-prescription market: 7%

[1] *Commission Report to the European Parliament and Council on the Application of Directives 92/73/EC and 92/74/EC, Brussels Com(97) 362 final*
[2] *Homeopathic and Anthroposophic Medicine in Europe: Facts and Figures Second Edition, 2007, ECHAMP*

The Characteristics of Homeopathic and Anthroposophic Medicinal Products

- Homeopathy and anthroposophic medicine work with the body's own forces to stimulate the healing process. They can be individually prescribed by a doctor or practitioner or in many cases selected for self-medication.

- Unlike conventional pharmaceutical medicines which interact at a physical level, these medicines are prescribed based on the study of the whole person, taking into account basic temperament and responses.

- Treatment is generally individualised and different people receive different treatments even if they suffer from the same disease. This individual and holistic approach meets a growing need for a more personalised way of healing.

- Homeopathic and anthroposophic medicinal products cover a broad portfolio of effective, safe and high quality medicines generally derived from natural substances.

- Unlike new chemical entities, homeopathic and anthroposophic medicinal products usually stem from well-known natural substances, which are then diluted. The concentration of the active principle(s) is very low compared to most conventional medicines.

- The individual therapeutic approach means that a large range of products is required, in particular by doctors and practitioners, mostly manufactured in small batches.

- These products are predominantly low cost, generic and not patentable, so registration or authorisation is regularly inhibited by disproportionate costs for application dossiers.

- Homeopathic and anthroposophic medical treatments are relatively inexpensive. These therapies have the potential to generate savings on health care costs.

URGENT REQUESTS

ECHAMP asks the European Parliament

to support the development of a harmonised and workable regulatory environment for homeopathic and anthroposophic medicinal products across the European Union;

to pass a Resolution that recognises

- the need to create a more appropriate regulation to allow market access for and free circulation of homeopathic and anthroposophic medicinal products in the EU
- the importance of homeopathy and anthroposophic medicine as therapeutic traditions and their role in improving healthcare in Europe
- the need to give priority to the demands of the European citizens who still have no access to the registered or authorised homeopathic or anthroposophic medicinal products of their choice
- the need to support the growth of this traditional and established EU-based industry so that homeopathy and anthroposophic medicine can continue to develop to the benefit of all citizens of Europe;

to call on the European Commission to

- carry out an in-depth assessment of the regulatory framework for homeopathic and anthroposophic medicinal products including a consultation of all the stakeholders, especially focussing on the issues mentioned in the Commission report of July 1997[1] and already included in the Report of the European Parliament dated 4 November 1998 on that Commission Report[2]
- make a proposal to the European Parliament and the Council to revise Directive 2001/83/EC in accordance with the conclusions of the Commission report and based on the experience of the competent authorities and stakeholders in the Member States
- enlarge the chapter on homeopathic medicinal products in Directive 2003/63/EC (Annex I) with requirements specific to the nature of these products avoiding the application of general rules for new chemical entities to homeopathic medicinal products
- create a Chapter 2b, 'Specific provisions applicable to anthroposophic medicinal products' in Directive 2001/83/EC, providing for an adequate authorisation or registration system for all anthroposophic medicinal products, making reference to the specific therapeutic approach in anthroposophic medicine
- urge the Member States to set up a common and affordable programme to bring all the homeopathic and anthroposophic medicinal products which were already on the market before December 1993 into an appropriate and harmonised regulatory framework
- urge the Member States to handle applications for homeopathic and anthroposophic medicinal products in a way that is proportionate to the low risk of these well-known and well-established products.

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[1] *Homeopathic Medicinal Products, Commission Report to the European Parliament and Council on the Application of Directives 92/73/EC and 92/74/EC, Brussels Com(97)362 final - C4-0484/97*

[2] *A4-0378/98 European Parliament Report on the Commission report to the European Parliament and the Council on the application of Directives 92/73/EEC and 982/74/EEC on homeopathic medicinal products (COM(97)0362 - C4-0484/97)*

The Need for an Improved Legal and Regulatory Framework

Homeopathic and anthroposophic medicinal products differ from conventional pharmaceuticals in a number of ways of relevance to an efficient and adequate regulation. European legislators have already recognised this by creating specific regulations for homeopathic medicinal products, as they subsequently did for traditional herbal medicinal products. However fifteen years of experience show that the legal framework for homeopathic and anthroposophic medicinal products is not adequately tailored to the particular characteristics of these products.

Lack of adequate European legislation has led to a significant reduction in the number of homeopathic and anthroposophic medicinal products on the market. The current regulatory framework functions successfully in only a minority of EU Member States. Rather than encouraging harmonisation, **it is restricting trade and industry development**. Doctors, practitioners, patients and consumers are being deprived of access to the medication of their choice in many Member States.

Homeopathic and anthroposophic medicinal products are intrinsically safe, low-concentration medicinal products and their characteristics are well-known. Failure to differentiate between the risks associated with conventional medicinal products, which are mostly of chemical origin, and the relative low risk potential of these products **leads to excessive regulatory requirements** that are inappropriate and to unnecessary work and cost for all parties involved.[1]

Nor does the regulation add significant value in terms of safeguarding public health. The tendency to overregulation favours the development of illegal parallel trade of low quality products from outside the European Union via e-commerce. The harmonisation process has been further **undermined by strong differences of interpretation** between the Member States.

[1] *For this reason, the application of Article 16(1) of Directive 2001/83/EC is not adequate. On the other hand, the optional nature of Article 16(2) leads to great differentiation in legal approaches by the Member States that is not in line with the EU goals of harmonisation and free trade for industrial products.*

Examples from the Member States

In 20 Member States, there are no published data on the number of registrations. In a large number of these Member States no products have so far been registered.

In the Netherlands, out of 11 000 notified products, less than 4 000 have been authorised or registered. The remaining products are no longer available for prescribers and users.

In Belgium, Italy and Spain no products have yet been registered or authorised, even though more than 15 000 products have been officially notified for registration or authorisation in each of these countries.

In the UK, of over 2700 products granted a license in 1973, less than 50 have been authorised. Out of more than 20 000 single remedies on the market, only 200 have been granted a simplified registration so far.

More than four years after it was introduced in Directive 2001/83/EC, only one product has been registered under the mutual recognition procedure, and that in only 3 Member States at once.

Products that are not accepted for registration or authorisation in one Member State may have market access in neighbour countries, leading to increasing disharmony and confusion for patients, prescribers and users.

The need for legal reform

Legal reform is urgently required to optimise the regime for these medicinal products. An adequate legal and regulatory framework should take account of their specific nature and low-risk profile. There is sufficient common ground in respect of the practice of homeopathy in the Member States to implement unified standards.

Simpler registration or authorisation requirements could be balanced with more consistent and appropriate post-marketing controls (pharmacovigilance), allowing the industry to document and standardise safety data and to confirm the positive safety profile of these products over a period of time. This approach would provide better protection for public health and be significantly more efficient.

Better regulation should ensure the availability of the full range of products prescribed by doctors and practitioners and demanded by patients, preserving homeopathy and anthroposophic medicine as important European medical traditions.

The European industry that provides good quality medicinal products for these therapies in accordance with the rules of Good Manufacturing Practice (GMP) should be fostered in its development, so that the positive health benefits of these therapies can spread. A better balance must be found between safeguarding public health and meeting the demands of the 100 million European citizens who choose to use these products.

Annex I provides ECHAMP's detailed recommendations for a more appropriate legal framework.

Four actions for an improved regulatory framework

ECHAMP strongly recommends four main actions for an improved EU regulatory framework for homeopathic and anthroposophic medicinal products:

- Develop more appropriate legislation based on the specific characteristics of the products
- Improve the efficiency of the regulatory environment by actively involving the stakeholders and experts in the field
- Simplify and harmonise the assessment environment; instigate work-sharing and accept some national agencies as specialised assessment centres for these products
- Balance a simpler system of registration or authorisation with an appropriate tailored pharmacovigilance system for all products, allowing the industry to generate and document safety data.

Annex I: ECHAMP's Specific Recommendations for Changes to the Current Legislation

1. Directive 2001/83/EC

Subject ***Article 1 (5): Definition of a homeopathic medicinal product***

Description of the **Problem**	*Proposal for a* ***Solution***	**Justification**
The use of the term 'homeopathic stock' is not precise. The definition leaves open the question as to whether it includes mother tinctures or not. This causes problems of interpretation by competent authorities in the Member States.	*Change the wording to make sure that all homeopathic medicinal products including homeopathic mother tinctures are fully covered by the definition.* *Let the packaging/labelling indicate whether it is a homeopathic medicinal product, a starting material or an intermediate product.*	Inadequate definition of key terms leads to differing interpretations, resulting in multiple problems. In accordance with homeopathic tradition, homeopathic stocks (mother tinctures) can be used as homeopathic medicinal products, as active substances or as starting materials for further processing.

Subject ***Article 13: Products covered by 'old' national registrations or authorisations***

Description of the **Problem**	*Proposal for a* ***Solution***	**Justification**
The meaning of 'except where such medicinal products are covered by a registration or authorisation granted in accordance with national legislation on or before 31 December 1993' is unclear. Sometimes the wording of this rule is used to take existing products off the market.	*Provide effective protection for products covered by former national registrations or authorisations in markets everywhere.* *Clarify the deadline especially for CEEC Member States.*	Member States differ in their interpretation of the legislation regarding the status of products on the market before 1993.

Subject ***Article 14 (1) 3rd indent: Degree of dilution***

Description of the **Problem**	*Proposal for a* ***Solution***	**Justification**
This condition is incomplete (it does not cover solid starting materials), non-scientific and open to divergent interpretation.	*Make use of the Comitology procedure mentioned in Article 14(1) to make the necessary changes. Introduce a proportionate and scientifically relevant approach for defining the safe degree of dilution.* *Where safety can be demonstrated, allow lower dilutions access to the special simplified registration procedure.*	Unclear definitions lead to varying interpretations on the safe degree of dilution. Many products are currently disappearing from the market even though there is no risk to public health. The legislation recognises this problem in the second paragraph of Article 14(1) which allows for modification of this article via Comitology. Lack of action will also lead to difficulties for mutual recognition.

Subject ***Article 14 (1) 1st indent: Route of administration***

Description of the **Problem**	*Proposal for a* ***Solution***	**Justification**
The special simplified registration procedure is restricted to oral and external routes of administration. Lack of definition as to what constitutes an oral or external route of administration leads to differences in implementation in the Member States. Common forms of administration are excluded from simplified registration, for example, injectables, which have been widely used for many years without additional risk to patients.	*Develop a solution for homeopathic and anthroposophic injectables without indications, largely used by practitioners: a simplified authorisation without therapeutic indications with the option of communicating that the medicinal product is intended for use in accordance with the principles of homeopathy and anthroposophic medicine; where appropriate this can be on prescription only or under the control of a recognised practitioner of homeopathic or anthroposophic medicine.*	Common forms of administration such as injectables are excluded from this legislation without scientific justification, and despite their high prescription rate and recorded safety. The difference in terms of risk between oral administration and subcutaneous administration is no higher than for conventional pharmaceuticals. The safety of this specific galenic formulation is guaranteed by rules for Good Manufacturing Practice applied during the

		manufacturing process of the ampoules; the prescription and use of these products under supervision of a recognised practitioner further reduces the risk. Safety of these products has been demonstrated in studies.

Subject ***Article 16(2) : Country specific marketing authorisation***

Description of the **Problem**	*Proposal for a **Solution***	**Justification**
Member States may introduce or retain specific rules for homeopathic medicinal products that are not covered by Article 14(1). Member States who implement Article 16(2) in accordance with their national tradition are defying harmonisation, hindering the free flow of products. Those who do not seriously cut back the product range. There is no provision for mutual recognition, so free trade of these products is not possible.	*Make compulsory the implementation of Article 16(2) for all Member States, thereby eliminating Article 16(1).* *Harmonise the specific pre-clinical and clinical data requirements for homeopathically-produced medicinal products in line with the principles and characteristics of homeopathy or anthroposophic medicine in Europe, taking into account the national traditions. The concepts of 'traditional use' and 'well-established use' in Directive 2001/83/EC may act as guiding concepts in this respect.* *Introduce a system of simplified mutual recognition for products authorised under 16(2) as is the case for Article 14(1) products.*	There are significant differences between the characteristics of homeopathic and anthroposophic medicines and those of conventional pharmaceuticals. Therefore the application of Article 16(1) is not adequate. The optional nature of Article 16(2) leads to great differentiation in legal approaches to products not eligible for the special simplified registration procedure. It is not in line with the EU goals of harmonisation and free trade for industrial products. There is sufficient common ground in respect of the practice of homeopathy in the Member States to define unified standards. The Directive itself recognises this where it says 'trials in accordance with the characteristics of homeopathy'.

Subject ***Provision for low potencies and injectables***

Description of the **Problem**	*Proposal for a **Solution***	**Justification**
The wording of Article 16(2) leads to different interpretations as regards an obligation to carry indications. Only some countries allow for authorisations without indication - to the detriment of low potencies and injectables	*Introduce a provision in Article 16 for homeopathic medicinal products not eligible for Article 14 as regards the safety level or the form of administration (i.e. low potencies or form of administration) but for which the applicant has good reasons for bringing the product to market without specific indications.* *Injectables authorised under this system might be made subject to practitioner prescription.*	With respect to mother tinctures, low potencies and injectables, which play an important role in the therapeutic range needed by practitioners, it is not always possible or relevant to define indications. The choice of medicine is made by the practitioner for the individual patient and based on the specific therapeutic approach of homeopathy or anthroposophic medicine.

Subject ***Article 16(3): Pharmacovigilance is not applicable to Article 14 products***

Description of the **Problem**	*Proposal for a **Solution***	**Justification**
This contradicts the principle of safeguarding public health; it also prevents the compilation of useful data on safety.	*Introduce a tailored pharmacovigilance system that includes all homeopathic and anthroposophic medicinal products, both registered and authorised. Ensure its realisation is proportionate to the sales levels and to the inherent low risk of these well-known products.*	Pharmacovigilance requirements for conventional pharmaceuticals are inconsistent and inappropriate. A single system will both supervise the market and generate comprehensive data as regards the safety and risk profile of these products.

Subject ***Article 69: Serious restriction on information to patients***

Description of the **Problem**	*Proposal for a* ***Solution***	**Justification**
Manufacturers cannot provide patients with basic information about the medicines. Users can get no information on how to use the products e.g. dosage and other essential user information.	*Under Article 69, allow for the basic information patients need for proper use of the medicinal product e.g. dosage and possible precautionary measures or points of special attention for the product.* *Also under Article 69, allow for reference to the particular therapeutic approach on packaging, leaflet and any further product information.*	This change is needed both to allow for the correct and safe use of the products and to harmonise the current divergent policy on packaging and labelling in the Member States. A divergent policy will cause additional problems for mutual recognition for these homeopathic remedies.

Subject ***Article 69(1) 11th indent***

Description of the **Problem**	*Proposal for a* ***Solution***	**Justification**
The current wording required by Indent 11 ('homeopathic medicinal product without approved therapeutic indication') sounds like a serious disclaimer, causing confusion for patients.	*Change wording to read: 'homeopathic medicinal product registered without specific therapeutic indications'.*	The current negative wording makes no sense and is incorrect and confusing to users. It is implemented and executed in divergent ways in the Member States and manufacturers are dependent on the individual interpretations of the national regulatory authorities..

Subject ***Article 100: Advertising***

Description of the **Problem**	*Proposal for a* ***Solution***	**Justification**
Certain countries restrict advertising/ information. This is not in accordance with the law.	*Allow distributors and manufacturers to provide doctors and practitioners with information on the specific therapeutic application of their products within a framework based on adequate bibliographic references or studies.* *Allow distributors and manufacturers to publish information for the general public regarding the therapeutic approach.*	Some markets continue to prohibit advertising despite changes in the law.

Subject ***Anthroposophic medicinal products***

Description of the **Problem**	*Proposal for a* ***Solution***	**Justification**
Anthroposophic medicinal products are not properly regulated; products may currently be regulated under different categories. This creates confusion and is misleading for the users.	*Create a new Chapter 2b 'Specific provisions applicable to anthroposophic medicinal products' in Directive 2001/83/EC, providing for a separate registration system for all anthroposophic medicinal products, making reference to the specific therapeutic approach in anthroposophic medicine.*	There is no uniform regime for the registration of anthroposophic medicinal products, despite the fact that these products are based on an established EU tradition. The most practical solution is to consider these medicinal products as a separate (third) category alongside homeopathic and herbal medicinal products.

Subject ***Provision for rarely prescribed homeopathic and anthroposophic medicinal products***

Description of the **Problem**	*Proposal for a* ***Solution***	**Justification**
There is no specific provision in the legislation for the supply of rarely-prescribed homeopathic or anthroposophic medicines, provoking illegal supply of these medicines mainly over the internet.	*Introduce a simple solution to allow the supply to pharmacists of seldom-prescribed homeopathic or anthroposophic medicines as special (magistral) preparations manufactured by the industrial manufacturers having a manufacturing license for these products.* *Introduce a provision or a special status for these products in Title II of the Directive. Make these products exempt from registration fees.*	Homeopathic practitioners use a large number of sometimes rarely-prescribed homeopathic medicinal products. They will continue to prescribe these products, which are an irreplaceable part of their therapeutic arsenal. This proposal would limit illegal supply and larify responsibility for the quality and the safety of these products guaranteeing as well their quality and safety. There are successful examples of such a system in Belgium, France and Germany among others.

Subject ***Braille - Article 56a***

Description of the **Problem**	*Proposal for a* ***Solution***	**Justification**
The requirements are not harmonised; moreover for Article 14 simplified registrations, it is technically almost impossible to add information in Braille on the sometimes very small packaging.	*Make exempt homeopathic medicinal products subject to simplified registration within Article 14 from the obligation for Braille within Article 56.*	Compliance with Braille requirements requires disproportionate and economically prohibitive investment considering both the broad range of batches per company and the extremely low number of blind users able to read Braille.

2. Directive 2003/63/EC (Annex I, Part III, Chapter 3): 'Homeopathic Medicinal Products'

Subject ***Chapter 3 in Annex I Part III needs improvement and completion with regard to homeopathic medicinal products***

Description of the **Problem**	*Proposal for a* ***Solution***	**Justification**
In many instances, the chapter on homeopathic medicinal products refers to the provisions for medicinal products in general. A one-to-one applicability does not take account of the specific characteristics of homeopathic medicinal products and leads to polarised interpretations in the Member States, from very flexible to very strict e.g. on stability testing and expiry date of the products and on 'missing data'.	*Enlarge the chapter with specific quality and safety provisions for homeopathic medicinal products, taking account of the particular characteristics of these medicinal products.* *This can be done via Comitology.*	Inadequate clarification of the criteria results in Member States practising individually developed rules for the assessment of the homeopathic dossiers and the quality and safety requirements, defying harmonisation. This will provoke major problems for mutual recognition.

Subject ***No definition on the justification of 'homeopathic use'***

Description of the **Problem**	*Proposal for a* ***Solution***	**Justification**
Member States differ in their interpretation as to what constitutes 'homeopathic use' or an adequate bibliography.	*Establish one uniform and compulsory regime that defines homeopathic use based on bibliography, tradition and documented experience from the different schools of homeopathy in Europe. This can be done via Comitology.*	Differences between Member States in determining what establishes homeopathic use result in disharmony and will lead to major problems for mutual recognition.

3. Mutual Recognition/Decentralised Procedure (Directive 2001/83/EC, Art. 27, 28 and 29, 1, 2 and 3)

Subject ***The use of the Mutual Recognition Procedure***

Description of the **Problem**	*Proposal for a* ***Solution***	**Justification**
There is no incentive to use the Mutual Recognition/Decentralised Procedures since the outcome is completely uncertain and the fees are much too high. Moreover, it is relevant only to Article 14 products, those without indications, which are of less commercial interest to the manufacturers. There is no harmonised approach amongst Member States as regards dossier structure (Common Technical Document) and requirements. Heavy assessment procedures and in particular an almost full re-assessment in the Concerned Member States lead to unnecessarily high costs and unaffordable high fees.	*Develop specific provisions for a simplified mutual recognition for homeopathic medicinal products within the Chapter 2 on homeopathic medicinal products.* *Ensure that the Concerned Member States (CMS) does not make a new assessment but accepts the file of the Reference Member State (RMS); allow opposition only in case of a serious risk to public health documented by the RMS.*	Standards applied in assessment for the Mutual Recognition/Decentralised Procedures should not be more demanding than those of regular national procedures. They should be in balance and the requirements should not be higher than needed for these well-known low concentration medicinal products. The accumulated fees are not affordable for the majority of medicinal products of these small and medium-sized enterprises because of their low turnover. Without a pragmatic solution, free trade and access for companies to new European markets will be blocked. Four years' experience since the implementation demonstrates the malfunctioning of the current procedure: - procedure is excessive; overregulation - no resources in the national agencies - not attractive for industry because of the disproportionate cost-benefit/high fees - the most important products - those with indications - are excluded.

4. Variations (Regulation 1084/2003)

Subject ***Omission of regulation for variations specific to homeopathic and anthroposophic medicinal products***

Description of the **Problem**	*Proposal for a* ***Solution***	**Justification**
The approach to variations lacks definition of typical variations in the field of homeopathic and anthroposophic medicinal products. The fees and time involved to manage a large number of minor variations are disproportionate without significant simplification of the system and reduction of administrative burden.	*Provide within Regulation 1084/2003 for specific rules that can cover in a practical way the variations that have to be done for these products, reducing administration and making use of the principles of work sharing and grouping of variations adapted to the specific variations that are needed for these products.*	Rules for variations are inappropriate and disproportionate for homeopathic medicinal products. Better regulation here will reduce the significant administrative burden. If homeopathic products are excluded from the regulation on variations as foreseen for other medicinal products, specific provisions for homeopathic medicinal products are needed because (mainly minor) variations are common for these applications.

Annex II: References

Bibliography

Homeopathic and Anthroposophic Medicinal Products in Europe: Proposals for Better Regulation, ECHAMP, 2008

EU Legislation

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, OJ L 297/8 [1992]

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use OJ L311/67 [2001]

Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ L 136/34 [2004]

Directive 2004/24/EC of the European Parliament and of the Council of 31 March 2004 amending as regards traditional herbal medicinal products, Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ L 136/34 [2004]

Commission Directive 2003/63/EC of 25 June 2003 amending Directive 2001/83/EC of the European Parliament and of the Council on the Community code relating to medicinal products for human use, OJ L 159/46 [2004] - Annex I to Directive 2001/83/EC

For an up to date overview of the implementation of this legislation in the Member States please visit www.echamp.eu.

ECHAMP, the *European Coalition on Homeopathic and Anthroposophic Medicinal Products*, represents the vast majority of the industry for these products in Europe. ECHAMP believes that homeopathy and anthroposophic medicine should be fully integrated into health care provision in Europe. It works towards an appropriate European legal and regulatory framework to ensure the availability of the full range of these medicinal products, essential for the successful practice and development of these long-standing traditional therapies.

ECHAMP has over 50 full (company) members. Its associated and corresponding members include national industry organisations and European associations of health care professionals, patients and consumers.

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