# Joint Position Paper on The Availability, Quality and Safety of Homeopathic Medicinal Products in Europe

***Views, needs and requirements of homeopathic practitioners prescribing single homeopathic medicinal products for the treatment of patients***

## Preamble and Summary

### What the subscribing organisations stand for

***Fundamentally: To ensure that patients have access to high-quality homeopathic treatment*** — this is the common aim of the organisations subscribing to this position paper, each organisation in its own way and in collaboration with the other.

This paper reflects the views of the professional and patient users of single homeopathic medicinal products. The paper does not cover the needs of other therapy methods that are subject to the same pharmaceutical legislation (e.g. the use of compound medicines, anthroposophic or spagyric preparations). However, their users' demands too must be respected and their concerns and requests formulated by competent experts. The authoring bodies of this paper are prepared for talks on a consensus for a common way forward.

### Rationale

Homeopathy is by definition a medicine based therapy that relies on an individualised prescription of a homeopathic medicinal product for each patient and their condition. Consequently a wide variety of homeopathic medicinal products of high quality in a full range of potencies are needed by practitioners in order to undertake successful homeopathic treatment. The recent significant and ongoing decline in the availability of the full range of homeopathic medicinal products in a growing number of European countries, despite the considerable efforts of producers of homeopathic medicinal products, has now created a serious situation that needs to be addressed.

This is not an issue about reimbursement of costs, but a real threat to patients' rights to have effective homeopathic treatment. Indispensable homeopathic medicines have already vanished from the market in a number of countries. This stands in contradiction to the very apparent interest of the public in homeopathic treatment. Surveys show that a steadily growing proportion of the public are seriously interested in receiving the benefits of complementary medicine in general and of homeopathic treatment in particular, whenever it is appropriate and possible.

In response to this serious situation the ECH and the ECCH have decided to combine their voices. Our main goal is to preserve the full range of single homeopathic medicinal products in high quality for the benefit of patients.

### Year to year more homeopathic medicinal products vanish

Revision of laws, new regulations and the increasing registration requirements on a European and national level have already resulted in a drastic reduction in the availability of the variety of homeopathic medicinal products in some countries. In particular, we are concerned about the maintenance of the availability of nosodes,

especially nosodes of human origin. According to surveys carried out by ECH and ECCH members associations, nosodes of human origin have a central and irreplaceable role in the “lege artis” homeopathic treatment of chronic diseases. For 200 years, these homeopathic medicines have been used successfully and no unfavourable effects have been recorded.

In a similar way we are concerned about the maintenance in availability of rarely prescribed yet nevertheless indispensable homeopathic medicines to the professionals. Excessive registration requirements and costs also threaten to prevent innovation in homeopathic treatment through preventing the introduction of new single homeopathic medicinal products made from materials not yet in use.

We understand the need for reasonable and comprehensible requirements for pharmaceutical drug safety. With regard to homeopathic medicinal potencies above a suitable potency level, however, we call for an exemption from safety regulations related to raw materials. Even in the case of biological raw materials, in our experience and understanding such requirements are not necessary for potentised medicines beyond a certain dilution level, each of which can be agreed on a case-by-case basis.

**To whom we address this paper**

First of all this paper is addressed to the EU Parliament, to the European Commission, to other responsible politicians and to regulatory authorities at both EU and National level. We also address this paper to patient and consumer organisations, and individual members of the public to point out the seriousness of the situation and to demonstrate the potential risk and loss to them from a health and therapeutic perspective.

In all questions regarding the quality of medicines, the producers are our first interlocutors and we address the paper to them too in the hope we can work together for the long-term maintenance of the full range of homeopathic medicinal products. With necessary recommendations to the homeopathic pharmacopeias also implied, we address this paper to the pharmacopoeia commissions as well.

**Why are so many different medicines necessary?**

Homeopathic treatment is based on selecting from among a currently existing 3000 + medicines, the one medicine which fits, according to holistic homeopathic criteria, the patient with his/her individual state of disease. During the course of homeopathic treatment of a single patient a number of different medicines may be needed. For a number of patients suffering the same diagnosed condition each patient may need a different individualised prescription. If the indicated medicine is not available to prescribe anymore, successful homeopathic treatment may not be possible.

In the experience of all homeopathy practitioners, nosodes are a very important category of homeopathic medicinal products necessary for treatment of chronic diseases. Their potential unavailability will have serious consequences for the successful homeopathic treatment of chronic conditions.

**What will be the consequences of this current development?**

The current development cannot be compared with the market adjustments of conventional pharmaceutical products, where dozens of medicines with the same active substance exist and where medicines come and go over time for various reasons. All homeopathic medicinal products remain continually potentially useful. Therefore the current annual loss of homeopathic medicinal products will be a burden carried by the patients, homeopathic physicians and homeopathic practitioners.

Patients are being hindered in their free choice of deciding which therapeutic method they would like and therapists can no longer choose freely, which method or medicine might help the patient most. Furthermore the potential long-term cost-benefit effects of

well-applied homeopathy cannot be developed in our health care systems, neither can they be validly compared with the spiraling costs of conventional pharmaceuticals.

**Our aims in brief are**

- to preserve access to the full range of homeopathic medicinal products used by homeopathic professionals.
- to ensure that patients and practitioners have the full range of homeopathic medicinal products available in excellent quality.
- to facilitate and support ongoing innovation in the sector of homeopathic medicinal products.

## (1) Availability, Permission, Registration

We appreciate the efforts of the producers to preserve homeopathic medicines. Nonetheless, in spite of considerable expenditure in time and money there has been an alarming loss in some product-sectors of homeopathic medicinal products. The associations of prescribers and patients therefore appeal to all those who are responsible politically and to the regulatory bodies on a national and European level, to support the following well-founded recommendations and demands.

(1.1) EU-Directives and other regulations must not result in restrictions to the production and the distribution of homeopathic medicinal products. Inappropriate medicine safety requirements and approval costs must not unreasonably impair the availability of homeopathic medicinal products.

(1.2) We therefore recommend emphatically that for each homeopathic medicine, or for groups of source substances, a safe dilution potency level be agreed above which the distribution of a homeopathic single medicine and a combination of them is possible without any further safety concerns. Two cases can be distinguished:
(a) the “First safe dilution” that is permitted to be distributed. This dilution should be calculated in relation to the maximum daily intake.
(b) a dilution grade “safe by dilution alone and per se, applicable to any homeopathic medicine derived from any raw substance, which allows together with GMP guidelines to produce safe medicines, without further safety requirements related to the raw substances.

(1.3) In this context, we recommend emphatically rational (within reasonable bounds) drug safety requirements for homeopathic end products exclusively, including biological medicines and nosodes.

> *For example*
>
> “Freedom from pathogenic agents” of the raw material is to be replaced by a rational risk assessment of the end product.

(1.4) We are especially concerned about nosodes, nosodes of human origin in particular, as well as about some homeopathic medicines of animal origin. Beside questions concerning the pharmacopoeias or the registration, there are major problems of obtaining raw materials due to the special requirements. Yet these substances are the sources of medicines that are an integral part of homeopathic science and practice. Surveys from the VKHD and from ECCH (see references) show that nosodes are indispensable in one third of the homeopathic treatments of all patients with chronic diseases. **In order to avoid restrictions in the freedom of access to effective homeopathic treatment, nosodes must be maintained in the full range necessary for effective treatment.**

(1.5) For a prescription according to the homeopathic law of similars, nosodes as well as other medicines are needed that are produced in a way that guarantees the best possible matching of the identity and state of the source material with that used to produce the originally proven homeopathic medicine (refer the section "Quality"). For the prescribers, this implies a need for remedies which are not treated in any denaturing or non-homeopathic way before, during or after the manufacturing process, and which are safe by dilution alone and per se.

Registration of lower potencies under partially different requirements is not affected by this. Single medicine homeopathic prescribers need high as well as low potencies, but unlike other medicines, they usually use nosodes in high potencies only (ECCH survey, see references). Taking into consideration the extremely different dilution grades, modified regulations should be created to permit the manufacturer to choose the lowest safe potency they want to bring onto the market, guaranteeing the safety of the final product by using acknowledged methods appropriate for the actual dilution grade.

(1.6) This creates the preconditions to facilitate the procurement of the raw materials in some cases. For example, the application of blood-donation regulations to nosodes of human derivation can be relinquished above a safe dilution grade which is to be determined.

***Further substantiation for "safety by dilution" is to be read in the annex 1***

(1.7) Full availability of future homeopathic medicinal products is to be guaranteed through simplified registration requirements without the inclusion of indications. Accordingly, these requirements should allow for adequate innovation and introduction of new homeopathic medicines.

(1.8) The mutual recognition process (MRP) must be realised speedily throughout Europe. National restrictions through administrative regulations undermining the MRP should be eliminated. The MRP should be applied in all EEA countries as well as other European countries that strive for the free exchange of goods.

(1.9) Registration should be extended to all potency types and grades as well as to all oral and other external pharmaceutical forms of a homeopathic medicine. This is to be included in the relevant pharmacopoeias.

(1.10) Homeopathic medicines made of narcotic and in some cases "non-marketable" raw materials should be made registrable starting with an appropriate potency.

## (2) Access to Homeopathic medicinal products

The following paragraph is about the necessity for patients to have free access to homeopathic medicinal products.

(2.1) A possible compulsory prescription obligation should – as applied in the past – only be applied to low potencies of toxicologically questionable products.

(2.2) We consider it essential that patients in each country have unrestricted access to homeopathic medicines that are marketable in other European countries.-

(2.3) The implementation of the EU Paediatric Medicines directive into the national law of Member States must not restrict or interfere with the application of traditional as well as new homeopathic medicinal products for the treatment of children of all ages.

(2.4) European authorities should work with the professionals and manufacturers to agree a realistic declaration of expiry dates for homeopathic medicinal products including semi-manufactured products and all intermediate potencies.

(2.5) The obligation to sell the full range of homeopathic medicinal products through pharmacies or under control of pharmacists exclusively is to be maintained or enforced.

## (3) Homeopathic medicinal products – gentle medicines for children

Homeopathy, also called the "gentle medicine", is very important especially in the treatment of children as well as pregnant or lactating women. In most European countries, homeopathy is appreciated as a comparatively safe option avoiding the side effects of conventional medicines, and thus suitable for sensitive populations like children.

Limitations to the use of homeopathic medicinal products, including new homeopathic medicines due to an inappropriate implementation of the European *Directive for paediatric use of medicinal products* are counterproductive and against the original intentions of the directive.

The "first safe dilution concept" already takes into consideration the special situation of weak and sensitive populations including metabolic differences, with ample safety margins. The requirement of additional data such as potential toxicity in children use makes sense for most conventional medicines, but is not appropriate for homeopathic medicines, in which there is no linear correlation between dosage and effect, and exceeds the provisions given in EC/2001/83, Art. 14. The same applies for the existence or non-existence of clinical data for the use in clinical conditions common in children. It is generally accepted that the indication of single homeopathic medicines is not derived from a diagnosis, but from the phenomenology of the total symptom picture of the patient.

Labeling of homeopathic medicines must not imply restrictions for the use for children or pregnant or lactating women, neither should it cause unsettlement or confusion in this aspect (compare section 5). Different dosage instructions esp. for low potencies are acceptable.

## (4) Quality of Homeopathic medicinal products

### (4.1) Starting position

We are well aware of the European Regulations and Pharmacopoeia. However most of these regulations were written for conventional medicinal products. While some of the content of these regulations is appropriate for homeopathic medicinal products in some respects the regulations are not appropriate. As a result homeopathic medicinal products are subjected to disproportionate and inappropriate requirements to ensure quality assurance that are not in the original spirit of the regulations. As a starting position for more specific explanations of the professional needs of the users, we wish to present a definition of quality that has been well discussed with the relevant stakeholders.

**We would like to specifically request that the expert opinions of the producers and professional prescribers are taken into account when creating and interpreting new regulations for homeopathic medicinal products. In order for this process to be fully effective some existing contents of the pharmacopoeia have to be adjusted, to ensure that the desired quality requirements are listed in the annexes.**

## (4.2) Definition

From a professional homeopathy practitioner's point of view the quality of a homeopathic medicinal product results from a combination of the following essential components:

*(a) The 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 as closely as possible.*

*(b) The proper and careful application of agreed homeopathic production methods appropriate for homeopathic medicinal products.*

*(c) Refraining from any treatment or influence, which is not part of the agreed homeopathic production methods for homeopathic medicinal products.*

## (4.3) Quality and Safety

The quality and safety needs of consumers and patients is naturally linked to our professional needs of providing safe and effective homeopathic treatment and also to the manufacturer's needs of having a continuing preparation for their products. Therefore when discussing medicinal quality it is essential to find solutions which are acceptable to all sides.

For the safety of nosodes, we refer to section 1.2 - 1.6 as well as to the annex. The current regulation regarding the preliminary treatment (thermic or other procedures) of what will eventually be high potency homeopathic medicines, which are based on certain biological substances, is in our opinion an unnecessarily heavy requirement and there is a high risk of significantly reducing the homeopathic quality of the medicines. On the standard regulatory understanding of quality this may be contestable, but from a homeopathic point of view this regulation is causing a potentially damaging situation regarding the quality and availability of homeopathic medicinal products.

**There is a strong need for high potencies from biological source materials including nosodes from non-denatured source materials, in order to be able to provide the best possible treatment for patients. We highly recommend that this need be accorded a legal status within the existing legislation and pharmacopoeia.**

## (4.4) The quality of the starting material

*"The raw material used for the production of a homeopathic medicinal product should match the raw material used in the original proving that gave rise to the materia medica of that medicine as closely as possible."*

To the usual criteria of identity, content, pureness, freshness and other mainly laboratory characteristics we wish to add another most important criteria: the best possible similarity between the starting material used for manufacturing the medicine and the originally proven substance. It is the fundamental need for an individual prescription made according to the law of similarity. There is no effective homeopathic treatment possible without it.

(Reference Grimm A. (2001), Die Pharmazie des homöopathischen Arzneimittels, in: Genneper/Wegener (2001), Lehrbuch der Homöopathie (Heidelberg) Ch. 21.7).

Manufacturers of homeopathic medicinal products should have reasonable options to choose which substance they might want to use for the production of homeopathic medicinal products. But their selection criteria have to be transparent and well documented as to which substance they use, especially if the producers are using a different variant or they deviate in any way from the originally proved substance, or if the literature on the original proving allows different conclusions.

Regarding the freshness of plant and animal substances it is unsatisfactory to categorize them just by the different dehydration characteristics according to the known monographs. We strongly recommend that producers create internal standards and once again stress that transparency and communication are the only way to ensure long-term quality.

**The following criteria are indispensable:**

(4.4.1) Raw source materials for homeopathic medicines have to match the originally proved material as closely as possible, any discrepancies are to be documented.

(4.4.2) Raw materials for homeopathic medicines are to be obtained with careful attention to and description of species, subspecies, stage of growth, parts of the plant used, wild or cultivated location and habitat. Detailed information on these matters should be available to the users on the producer's homepage.

(4.4.3) Divergent raw materials for homeopathic medicines for well-justified reasons should be allowed, but have to be declared precisely for users and patients. A short reference should be sufficient for labelling, more detailed information should be available on the producer's homepage.

(4.4.4) It should remain optional whether to use cultivated or wild plants and animals. Accordingly, the protection/conservation of species is to be considered with regard to the amount actually needed.

(4.4.5) GACP (Good Agricultural and Collection Practices) Guidelines are to be applied and – if necessary modified - according to the peculiarities of homeopathy.

(3.4.6) GMP (Good Manufacturing Practice) Guidelines are to be adapted in a way appropriate for homeopathy, because the standards useful for chemically defined medicines do not always make sense with regard to homeopathic medicinal products. As a long term solution, a set of specific guidelines called Homeopathic Good Manufacturing Practice (for industry) and Homeopathic Good Preparation Practice (for pharmacies should be developed.

(4.4.7) Nomenclature:

There are two relevant nomenclature systems: The traditional homeopathic nomenclature and a nomenclature derived from the prevailing scientific systems of classification. Additionally, in different countries different names have been used. A revision is being discussed.

For the foreseeable future therefore we suggest using

**(a)** a nomenclature following the prevailing scientific nomenclature system for all new homeopathic medicines,

**(b)** for all existing homeopathic medicines where it would make a difference to nomenclature, to mention both the name traditionally used in each country and the scientific name.

A revision of the nomenclature must not lead to the loss of traditionally used medicine names. This includes traditional created names e.g. Causticum hahnemanni which have to be maintained as well. Further work is needed to determine how both the traditional and the scientific nomenclature system can be used in a way that is compatible with the relevant pharmacy legislation.

## (4.5) The quality of manufacturing

*"The proper and careful application of agreed production methods for homeopathic medicinal products."*

Homeopathic professionals regard the details of preparation listed below to be essential for the homeopathic quality of the product. As far as they are not included in the official pharmacopeias, we request full transparency on the following matters in order to allow informed decisions to be made by the prescriber:

- immediate processing of plant and animal substances; immediate processing of pre-processed products like mash into a more stable form.
- the method used for creating the first potencies. (trituration or succussion)
- number and intensity of the strokes used for succussion and respectively the intensity of trituration
- size of bottles, what kind of bottles and how much space is left to dynamise
- quality and percentage of the ethanol used
- quality and size of the globuli used
- avoiding contamination and non-homeopathic influences (ref. 3.6).

Today's quality and safety requirements are already causing high costs and yet considerably miss the goal. Important aspects regarding the quality of homeopathic medicinal products are still not considered in the official pharmacopoeias or anywhere else. Again we'd like to stress that transparency and communication of the producers with the prescribers are the only ways to ensure long-term quality and sustainability.

**Our recommendations on manufacturing methods in detail:**

(4.5.1) Some variation in production processes should be possible, as far as such processes are listed in the literature or can plausibly be justified. Precise declaration is demanded also in this case. The declaration can, if necessary, be made by corresponding identification codes which refer to recorded documentation of the details. Detailed information should be available on the producer's homepage.

Explanation for 3.5.1 in connection with 3.4.3
In some cases (e.g., Causticum), different varieties are historically and/or methodologically justifiable. Users should have the possibility to make a decision based on information provided.

(4.5.2) Fresh triturations of all trituratable materials and "Single-glass-method" (Korsakov-Method) are production methods to be included in the European Pharmacopoeia and, if necessary, in the relevant monographs as well.

**Justification for fresh trituration of all trituratable materials:**
The fresh trituration or direct trituration of all technically trituratable materials is desired by homeopaths for reasons of quality. A trituration contains all ingredients of the source material, whereas a tincture contains only a selection depending on solubility and differs in composition.

**Justification for single-glass potentisation:**
The production of high potencies higher than 1000c is technically possible only if the "Single-glass-method" is applied in the manufacturing process when going beyond a specific potency level – a procedure explicitly agreed by Samuel Hahnemann and internationally used until the present day. Limitation to the multi-glass method as the only agreed method would lead to the loss of high potencies like e.g. 10.000c which are used by many homeopaths.

### (4.6) Avoiding disturbing, non-homeopathic influences

*"Refraining from any treatment or influence which is not part of the agreed production method for homeopathic medicinal products."*

As such we summarize:

- Contamination with other potencies – e.g. during the process of impregnation of globuli or using tools which were used to manufacture other homeopathic medicinal products and are not sufficiently cleansed.
- Any denaturising treatment of the substance is to be avoided except methods of dehydration, extraction and trituration, which are specifically listed in the pharmacopeias.
- Heating, radiating or chemical treatment of the source substance, intermediate potencies or final product is to be avoided.
- Chemical as well as physical disturbances e.g. strong electro-magnetic fields, direct sunlight, heat, strong odours etc are to be avoided as far as possible. This includes storage conditions.

Our quality criteria for raw material and manufacturing in some ways already include the need to keep all stages of the production process free from such influences as far as possible. Nevertheless, we mention it explicitly for two reasons: 1st, storage has to be considered as well and secondly we wanted to stress once more the need of the prescribers and patients for effective active homeopathic medicines.

**Our most important concern:**

As mentioned in 3.3 there exists a need for high potencies made from non-processed source materials including nosodes among the professionals. We highly recommend giving this need a legal status. In addition to this we rely on transparency from the side of the manufacturers.

## (5) Required labelling statements on Homeopathic medicinal products

Also here, the professionals call for transparency and non-discrimination:

(5.1) A legally required warning notice is to be kept independent of any single profession, e.g. "the patient should seek professional advice if the symptoms persist while taking the medicine".

> Explanation:
>
> In some European countries, it is not only medical practitioners who prescribe homeopathic medicinal products.

(5.2) The declaration should not leave an impression of discrimination with the patient. Our recommended wording: "Medicinal Product for Homeopathic Treatment"

(5.3) As demanded in Section (4), all relevant information concerning the raw materials, the origin and production should be accessible for professionals on demand, e.g. through the internet.

(5.4) We demand exclusion of homeopathic medicinal products from all restricting or potentially unsettling instructions for children as well as for pregnant or lactating women (compare section 3).

(5.5.) The issue of dosage instructions for homeopathic single medicines is disputed. However, when the legal framework requires dosage instructions, the reservation is to be added *"if not prescribed differently"*.

## (6) Regulations used in certain Countries recommended as a basis for EU, EEC and EFTA wide application by all National Medicines Authorities

Different solutions have been found within Europe, including non EU member states, of how to regulate and register homeopathic medicinal products. In this section we refer to solutions which have been developed in countries with a long homeopathic tradition and which bring together the public needs for safety, high quality and availability of homeopathic medicinal products in a pragmatic way. We strongly recommend making use of these solutions in developing regulations in other European countries and introducing general guidance derived from them into the European framework as well.

### (6.1) The Swiss regulations – a pragmatic approach

The Swiss Swissmedic agency has been in close communication with all groups of stakeholders to work out their current system for registration of homeopathic medicinal products. In comparing the different systems we consider the Swiss regulations are those that as a whole come closest to achieving the above-mentioned aim of meeting the "needs for safety, high quality and availability of homeopathic medicinal products in a pragmatic way". This is due especially to the following aspects:

— Besides the simplified registration procedure, there is a so-called 'notification procedure' (Meldeverfahren). The notification procedure is much more simple and is applicable for agreed minimum dilutions.

— The agreed minimum dilution grades for both the simplified registration procedure and the notification procedure are published in a special list (HAS list). This HAS list can be amended, if a literature dossier is added.

— This system allows the flexibility to take into account different application forms as well as the very different needs for low, medium and high potencies.

— This applies also for so-called 'biologicals' and for nosodes (KPAV Art. 11 including 11.4) , provided a HAB Monograph is available for this medicine. If not, a monograph has to be developed for notification.

— The "Directive on the simplified registration procedure for complementary and herbal medicine, KPAV" meets the regulatory needs of very different groups of complementary medicine.

— The registration fees are feasible with about 500 sFr and allow the maintained availability of the large number of medicines that are needed for high quality homeopathic treatment (Heilmittel-Gebührenverordnung HGebV). It is possible to submit master-dossiers for certain groups of homeopathic medicines it, but this is handled quite divergently for different groups.

— Transparency: The Swissmedic approach meets the regulatory needs in a comparatively clear and simple way.

However, we are carefully watching developments after Swiss colleagues have reported a change to a stricter regimen in the registration of homeopathic medicines in recent times. All the regulations are published on the Swissmedic website www.swissmedic.ch.

### (6.2) German regulations – the "rule of 1000"

A practical solution in the German regulatory system is the so called "rule of 1000" which allows the production of up to 1000 units of a medicine per year with a simple notification. However, the manufacturer must be able to present all the documentation needed for normal registration on request. For the production of OTC medicinal products by pharmacies there is a similar "rule of 100".

In 2001, both the "rule of 1000" and the "rule of 100" were restricted to medicines of non-biological and non-animal origin. **This revised ruling was one of the reasons for**

**the loss of many essential homeopathic medicinal products in Germany. In our considered opinion this rule should be repealed. For reasons already given in this document the risks from medicines of biological origin are non-existent in homeopathic medicinal products above agreed potency levels and produced according to good GMP and pharmacopoeia criteria.**

### (6.3) The magistral prescription / Several regulations

In countries like Spain, UK and the Netherlands, specific pharmacies are authorised to prepare delegated magistral and offical homeopathic preparations. This authorisation should be implemented in legislation throughout the European community.

Legislation affecting raw materials and stocks must guarantee full availability of all stocks found in homeopathic literature, and must foresee procedures for methodology and safety to keep isotherapeutic treatment available.

### (6.4) UK regulations – full availability, Korsakov included

The UK system is another good example of a pragmatic regulatory system for single homeopathic medicinal products, which allows the continuing availability of the full range of single homeopathic medicinal products for the use of practitioners and patients. This system includes Korsakov (single glass) potencies that can be produced according the pharmacopoeias used in the UK.

## Annex 1: Safety by Dilution

### 1. Different dilutions and safety levels

Dilution is the essential reason that the safety of homeopathic medicinal products can be guaranteed in a different way than for other medicines. The amended EU Directive on pharmaceuticals for human use (2001/83/EC) already recognises this fact in that it sets an across the board 'first safe dilution' of one part in 10,000 for all single homeopathic medicines. However, the dilution grades of medicines prescribed by homeopathic professionals vary greatly. The different dilution grades have to be taken into consideration in an appropriate way. At the same time, simple regulations are needed. Mostly following the Swiss regulatory system, we propose to distinguish the following dilution grades for different safety levels of homeopathic medicine:

(a) 1st producible safe dilution

(b) 1st dilution "safe by dilution alone and per se", worst case: log $10^{-23}$ (23x / 12c) and above,

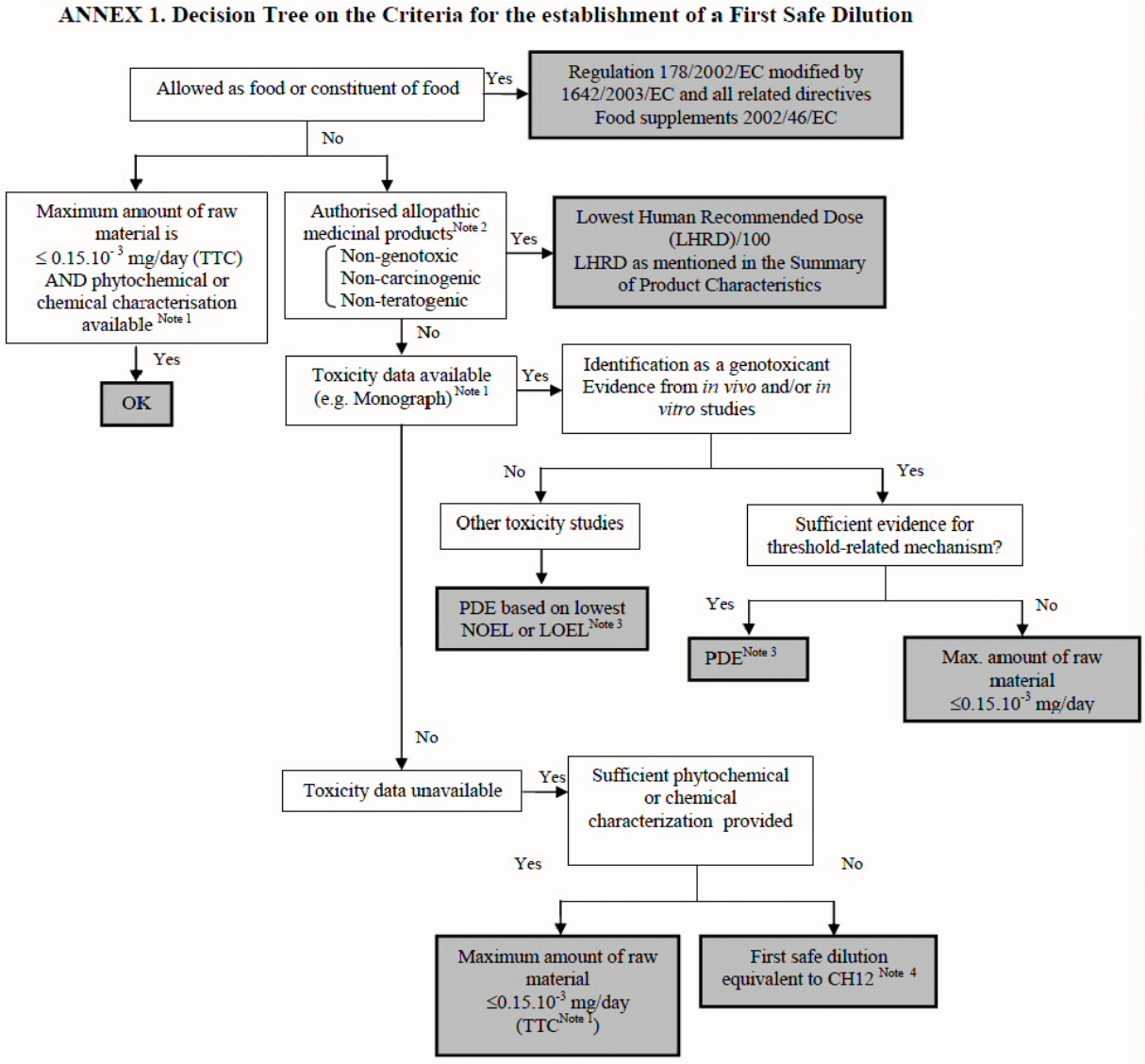
It is our strong recommendation that risk assessment of homeopathic medicinal products should exclusively be related to the end product.

The regulatory system in most European countries already follows the 1st safe dilution concept or is going to introduce it. However, the distinction of a safety level based on log $10^{-23}$ (23x / 12c) and above dilutions, which allows more simplified regulations and provides safety for homeopathic medicines from whatever source material alone by dilution, may need some explanation.

### 2. Rational for Safety by Dilution alone and per se

Depletion is the most effective method to exclude infectiousness. From a scientific point of view, safety can only be defined in mathematical terms, i.e. as a probability quotient. The advantage of potentising according to Hahnemann's method is that it includes fewer imponderables in the calculation of risks than other well-established methods. Different from other methods, Hahnemann's potentising method allows for a direct calculation of the risk even without providing evidence through experiments. Even in a worst-case scenario and in requiring an additional "safety margin", a dilution of log $10^{-23}$ (C12/D23) and above can be counted as safe.

The HMPWG paper *"Points to consider on non-clinical safety of homeopathic medicinal products of botanical, mineral and chemical origin for human use"* follows this logic in the diagram in its appendix, which in principle is applicable for all groups of source substances. Here below is the flow chart of the HMPWG paper as published on the HMA website in July 2007:




We confidently predict that for almost all homeopathic medicines substantially lower dilutions can be considered safe through “dilution alone and per se” given a rational risk assessment of the end product.

Analyzing experiments, A. Immelmann came to the same conclusion in his paper: “Viral Safety Evaluation of Biopharmaceuticals and Homeopathic Preparations of Human or Animal Origin” (Pharmeuropa Scientific Notes, 2006-1): *”Finally it could be shown that the process of potentisation with the successive dilution leads to an attenuation, i.e. removal of the virus, in accordance with the dilution of the starting material.”* Experiments have shown that depletion of the virus in the process of potentisation seems to be an effect, but that has not been further explained in this paper. There seems to exist non-published data of importance, which confirms the conclusion that the method of successive dilution alone can lead to the required medicinal safety.

Methods to inactivate the virus by heat or other procedures can only reduce the active virus and can only be assessed in quantity (A. Immelmann Fig. 1 and 2). The elimination of the virus by successive dilution is the only method that is applicable to any kind of virus. It has to be deductible that shelled and non-shelled viruses and even prions or theoretically possible unknown transmissible agents show the same results. The relevant data will be widely transferable.

In literature a number of references can be found from which it is clear that infectiousness and toxicity are concentration-related. It can be shown that pathogenicity disappears below scientifically definable minimum concentration.

GMP-guidelines allow safety measurements for employees regarding hazardous products as applied in the production of vaccines. “Safety by dilution” may not be the cheapest and easiest way. The manufacturer’s decision to produce and to sell such homeopathic medicines should be left to the free market.

On the side of homeopathic prescribers there is a huge demand for homeopathic medicines of animal origin and nosodes that are produced from non-denatured material. This corresponds to their homeopathic understanding of medicinal quality. The best possible match of the raw material and the substance documented by the original homeopathic provings is and always will be a main factor. The growing interest of the user in medicinal quality can also be an opportunity for the producers. We highly recommend giving this demand for non-denatured medicines a legal status and not to leave this field to illegal imports of dubious origin.

## 3. Summary and Conclusion

The depletion of pathogenic substances to a point near zero is a logical and realisable concept for the safety of the final homeopathic medicinal product. We assert that the method of “safety by dilution” is superior compared to the other methods. First of all because it doesn't require denatured substances and secondly it affects all viruses the same way regardless of their known resistance. The combination of dilution and thermal inactivation of source substances of hazardous origin may not be avoidable for production of low potencies, but for high potencies “safety through dilution alone” is absolutely efficient and meets the safety criteria or even goes beyond them. Ultimately it is the scientifically founded decision of the producer what way will ensure medicinal safety.

Based on a rational risk evaluation of the final product we can assume that in most cases homeopathic medicines that are diluted below $\log10^{-23}$ (D23/ C12) can be safely produced by dilution alone and per se. The current request for dilution grades above D23 is justified more for psychological and political reasons than for justifiably rational ones. **The subscribing organisations of this paper can therefore accept for the interim C30 ($\log10^{-60}$) dilutions as a possible limit to completely guarantee safety, until further research proves that lower potencies equally provide “safety alone by dilution” irrespective of the source material.**

## Literature


Hahnemann S. (1833) *Organon of Healing Art* (5th ed.), §§ 264 – 271. Dresden / Leipzig: Arnold'sche Buchhandlung

Hahnemann S. (1921) *Organon of Healing Art*, (6th ed.), §§ 264 - 271. Leizig: Schwabe

Hahnemann S. (1822/1830) *Materia Medica Pura* (div. prefaces). Dresden: Arnold'sche Buchhandlung

Hahnemann S (1828) *The Chronic diseases* (Vol. 1, Section „the medicines" and prefaces of the other volumes) . Dresden / Leipzig: Arnold'sche Buchhandlung

Jahr G.H.G. (1857) *Doctrines and Principles*, §§ 133 – 147, . Stuttgart: Verlag von Samuel Gottlieb Liesching

Hering C. (1877) Our Nosodes (I). *North American Homeopathic Journal*, Aug, 109-115.

Hering C. (1880) Our Nosodes (II). *North American Homeopathic Journal*, Aug, 88-93.

Hering C. (1881) Some Remarks on Psorinum. *North American Homeopathic Journal*, Feb, 477-482.

Swan S. (1888) *A materia medica of nosodes and morbific products*. New York : Press of Pusey & Co

Grimm, A. (2001) Die Pharmazie des homöopathischen Arzneimittels, in: Genneper/Wegener, *Lehrbuch der Homöopathie*, Heidelberg: Haug-Verlag Ch. 21.7

European Council for Classical Homoepathy (ECCH). (2005) *The Availability and Quality of Homeopathic Medicinal Products in Europe*, (2nd ed.) Nov. [online] last accessed 10 September 2008 at URL http://www.homeopathy-ecch.eu

European Council for Classical Homoepathy (ECCH). (2008) *Nosodes in Homeopathy Practice – An ECCH Survey*. [online] last accessed 10 September 2008 at URL http://www.homeopathy-ecch.eu

Homeopathic Medicine Products Working Group (HMPWG) (2007) *Draft "Points to consider on non-clinical safety of homeopathic medicinal products of botanical, mineral and chemical origin for human use*".

Verband Klassischer Homöopathen Deutschlands (VKHD). (2006) *Nosodes in the Homeopathic Practice, a survey of the VKHD*. *Homöopathie-Zeitschrift*.

European Coalition of Homeopathic and Anthroposophic Medicine Producers (ECHAMP) (2006) *Nosodes in Homeopathy: Significant and Safe*.

Immelmann A. (2006) Viral Safety Evaluation of Biopharmaceuticals and Homeopathic Preparations of Human or Animal Origin. *Pharmeuropa Scientific Notes*


## Editors / Imprint


ECCH European Central Council of Homeopaths
School House, Market Place, Kenninghall
Norfolk NR16 2AH United Kingdom
www.homeopathy-ecch.eu

ECH European Committee of Homeopathy
Chaussee de Bruxelles 132, Box 1
1190 Brussels, Belgium
www.homeopathyeurope.org

Revised Edition 2010