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 others.

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 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 on 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 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 nosodesof human origin have a central and irreplaceable role in the "lege artis" homeopathic treatment of chronic diseases. For 200 years, these 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 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 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 responsible politicians and 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 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 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 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. (2)

Our aims in brief are

- to preserve access to the full materia medica of homeopathic medicinal products
- to ensure that patients and practitioners have the full range of homeopathic medicinal products available in excellent quality (quality also implies safety).
- 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 our 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", which allows in general and in particular for nosodes to be produced as safe medicines without any denaturing or non-homeopathic pharmacopoeia required procedure and without further safety requirements related to the raw materials.

(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 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. A survey from the VKHD (see references) shows that nosodes are indispensable in one third of the 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 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. 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 according to their understanding of the nature of each medicine.

(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

(1.8) 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 medicines.

(1.9) 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 also be applied in those European countries outside the EU, which strive for the free exchange of goods (e.g., Switzerland, Norway, Croatia)

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

(1.11) Medicines from "non-marketable" narcotics (Europe: made of narcotic 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. Homeopathy, also called the "gentle medicine", is very important especially in the treatment of children as well as pregnant or lactating women. Limitations to the use of homeopathic medicinal products, including new medicines due to the implementation of the European *Directive for paediatric use of medicinal products* are counterproductive and against the original intentions of the directive.

(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 have unrestricted access to medicines which 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) Quality of Homeopathic medicinal products

3.1 Starting position

We are aware of the regulations governing the quality of medicines in national and European Regulations, (e.g GACP and GMP guidelines, CMPC-documents and pharmacopoeia regulations). However all these regulations were written for conventional medical 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 opinion 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.

3.2 Definition

From a medical professional 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.

3.3 Quality and Safety

The quality and safety needs of consumers and patients is naturally linked to our professional needs of providing safe and effective treatment and also to the manufacturers 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 medicines, which are based on certain biological substances, is in our opinion an unnecessarily heavy requirement and there is a significant 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 among the professionals for high potencies from biological source materials including nosodes from non-denatured source materials. We highly recommend that this need be accorded a legal status within the existing legislation and pharmacopoeia.

3.4 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 *** e.g. Andreas Grimm (Lehrbuch der Homöopathie/Genneper-Wegener; Chapter 21.7) .

Manufacturers of homeopathic medicinal products have the freedom 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.

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:

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

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

(3.4.3) Divergent raw materials for medicines for well-justified reasons should be allowed, but have to be declared precisely for users and patients. Detailed information should be available on the producer's homepage.

(3.4.4) 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.

(3.4.5) 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. <u>We would propose in fact that a set of specific guidelines called Homeopathic Good Manufacturing Practice (for industry) and Homeopathic Good Preparation Practices (for pharmacies) are developed.</u>

(3.4.7) 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 medicines,

(b) for all existing 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 which is compatible with the relevant pharmacy legislation.

<u>3.5 The quality of manufacturing</u>

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

The following preparation procedures should be considered to be included into the official pharmacopoeia with regard to homeopathic preparations:

- 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 versus 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 used ethanol
- quality and size of the used globuli
- avoiding contamination and non-homeopathic influences (ref. 3.6).

Today's quality safety measurements are already causing high costs and yet considerably missing 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 way to ensure long-term quality and sustainability.

Our recommendations to manufacturing methods in Detail:

(3.5.1) 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 3.1 – 3.4:
In some cases (e.g., Causticum), different varieties are historically and/or methodically justifiable. Users should have the possibility to make a decision based on information.

(3.5.2) Fresh triturations of all trituratable materials and "Single-glass-method" (Korsakov-Method) are to be included in the European Pharmacopoeia.

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 to achieve each specific potency level – a procedure explicitly agreed by Samuel Hahnemann and 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.

3.6 No 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 and extraction, which are specifically listed in the pharmacopeias.
- Heating, radiating or chemical treatment of the substance, intermediate potencies or final product is to be avoided as far as possible.
- 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 include already the need to keep all stages of the production process free from such influences as far as possible. Nevertheless, for two reasons we mention it explicitly: 1st, storage has to be considered as well and secondly we wanted to stress once more the need of the therapists for effective active medicines.

Our most important concern:

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

(4) Declaration of Homeopathic medicinal products

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

(4.1) A 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, homeopathic medicinal products are not only prescribed by medical practitioners.

(4.2) The declaration should not leave a discriminating impression on the patient. Possible wording: "Medicinal Product for Homeopathic Treatment"

(4.3) As demanded in Section (3), all relevant information concerning the raw materials, the origin and production should be accessible for professionals on demand, e.g. through the internet.

(4.4) We demand exclusion of discriminating instructions for children's use of homeopathic medicinal products.

(5) 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 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 other European countries and in introducing general guidance derived from them into the European framework as well.

5.1 The Swiss regulations – a pragmatic approach

The Swiss Swissmedic agency has been in a close communication with all groups of stakeholders to work out their current very pragmatic system for registration. In comparing the different systems we consider the Swiss regulations are those that as a whole are the 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:

— Beside 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 easily be amended.

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

— This applies also for so-called 'biologicals' and for nosodes (KPAV Art. 11 including 11.4).

— 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 very fair and allow the maintained availability of the large number of medicines that are needed for high quality homeopathic treatment (Heilmittel-

Gebührenverordnung HGebV).

— Transparency: The Swissmedic approach meets the regulatory needs in a comparatively clear and simple way. All the regulations are published on the Swissmedic website www.swissmedic.ch.

5.2 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 OTC (?) 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 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.**

5.3 Several regulations – the magistral prescription

Magistral prescription is possible in several countries. Austria allows a wide application ... ***(to be completed)*** *needs Austrian input !*

In countries like Spain, UK and the Netherlands, specific pharmacies can be authorised to prepare delegated magistrals and even officinal preparations. This authorisation has to be implemented in legislation throughout the European community. Legislation on 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.

5.4 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 pharmacopeias used in the UK.

Annex: 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) below the 1st safe dilution

(b) 1st safe dilution and above, but below log 10^{-23} (23x / 12c)

(c) log 10^{-23} (23x / 12c) and above

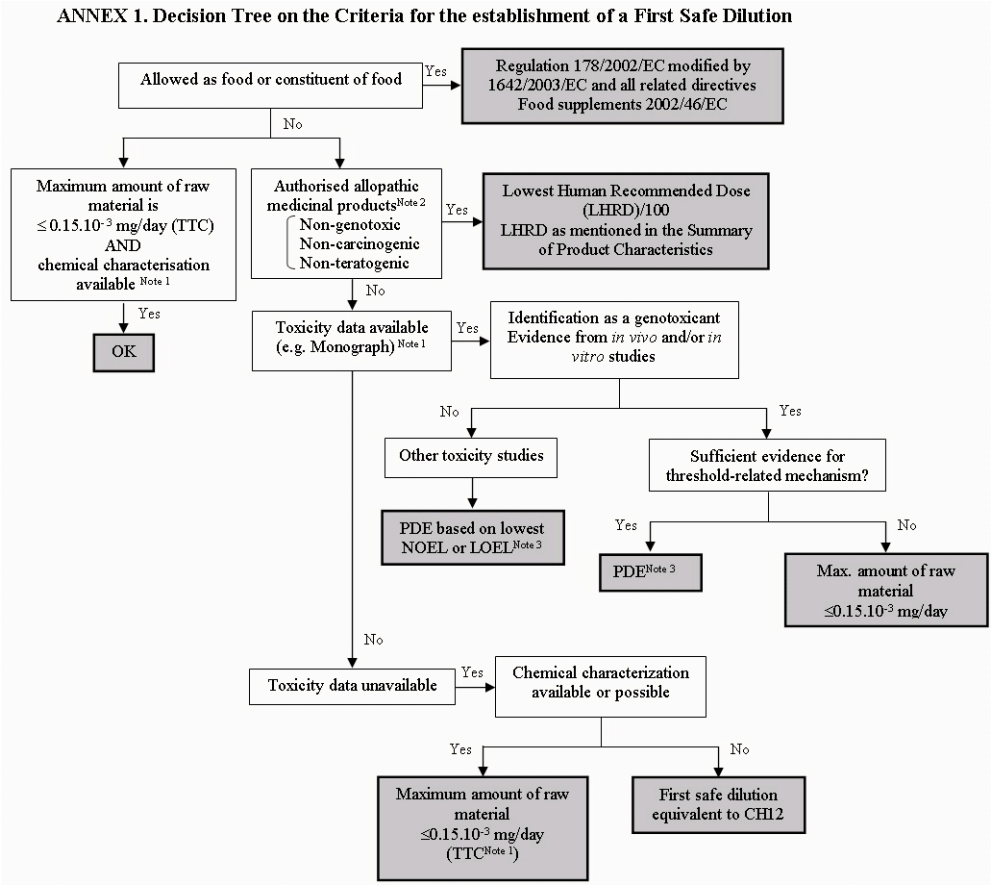
The regulatory system in most European countries already follows the 1st safe dilution concept or is going to introduce it. However, the distinction of a safety level based on log 10^{-23} (23x / 12c) and above dilutions, which allows more simplified regulations and provides safety

for 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 draft 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 according to the present state of discussion:



We confidently predict that for almost all 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 medicine 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 medicines should be left to the free market.

On the side of homeopathic prescribers there is a huge demand for 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 educated decision of the producer that will ensure medicinal safety.

Based on a rational risk evaluation of the final product we can assume that in most cases 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 rather 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.**

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