

Injectables for Subcutaneous Administration as used in Homeopathic and Anthroposophic Medicine

Position Paper 2003/02

A study by the ECHAMP Working Party Pharmacotechnical Affairs

Including Statements from Doctors Associations

European Committee for Homeopathy - ECH (20 European associations)

European Council of Doctors for Plurality in Medicine - ECPM (46 European associations)

International Federation of Anthroposophical Medical Associations - IVAA (11 European associations)

The International Society of Homotoxicology (13 associations)

The International Society for Biological Medicine

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Summary

The subcutaneous use of Homeopathic injectables is safe and effective. These products have been used since more than 50 years in Homeopathic and Anthroposophic medicine.

Directive 2001/83 EC foresees that Homeopathic medicinal products for subcutaneous use have to undergo the procedure for Marketing Authorization.

International medical umbrella organisations such as

1. European Committee for Homeopathy - ECH (20 European associations)
2. European Council of Doctors for Plurality in Medicine - ECPM (46 European associations)
3. International Federation of Anthroposophical Medical Associations - IVAA (11 European associations)
4. International Society of Homotoxicology (13 European associations)
5. International Society of Biological Medicine

strongly express the **need** of their members to be able to prescribe **Homeopathic injectables for subcutaneous use** in future.

The considerable total sales numbers (more than

60 millions of Homeopathic ampoules sold per year) reflect the need of medicinal products for subcutaneous use.

To fulfil needs of these prescribers the Homeopathic and Anthroposophic industry produces a great quantity of different medicinal products in very small batches. The production costs are thus high. Therefore the Homeopathic industry cannot afford the costs of a marketing authorisation procedure for all medicinal products needed in Homeopathic and Anthroposophic medicine.

Only if the Homeopathic “simplified” registration procedure, which is less costly can be applied to Homeopathic medicinal products for subcutaneous use, would the Homeopathic industry afford to keep these products on the market, ensuring the availability for the patients.

There is little evidence to show that there are any risks associated with the use of Homeopathic medicinal products by subcutaneous injection.

In reality very few adverse reactions to Homeopathic medicinal products for subcutaneous use have been reported, as illustrated in the following Table:

<i>Manufacturer</i>	<i>Number of ampoules sold</i>	<i>Ampoule volume</i>	<i>Mode of administration</i>	<i>Number of adverse reactions</i>
<i>1st Anthropos. manufacturer</i>	<i>105 million in 10 years</i>	<i>1 ml and 10 ml</i>	<i>s.c. (98%), i.m. and i.v. (2%)</i>	<i>13</i>
<i>2nd Anthropos. manufacturer</i>	<i>80 million in 10 years</i>	<i>1 ml</i>	<i>s.c. (98%), i.c., i.v., i.m. (2%)</i>	<i>23</i>
<i>Homeopathic manufacturer</i>	<i>350 million in 5 years</i>	<i>1 ml and 2 ml</i>	<i>s.c. (ca. 60%), i.v., i.c., i.m., intraarticular and periarticular (about 40%)</i>	<i>22, of which s.c. 6 times i.v. 2 times i.m. 8 times intraartic. 3 times periartic. 3 times</i>

The EU legislators are asked to set up regulations that will guarantee the interests of doctors, patients and manufacturers of Homeopathic injectables for subcutaneous use, by including ampoules for subcutaneous use within the range of possibility of the simplified registration category during the Review of Directive 2001/83 EC.

1. INTRODUCTION

1.1 Key Positions

For prescribers and patients in the EU it is necessary that Homeopathic injections for subcutaneous administration as used in Homeopathic and Anthroposophic medicine stay available.

Only if the Homeopathic “simplified” registration procedure will become applicable to Homeopathic medicinal products for subcutaneous use, this will be possible. The subcutaneous use of Homeopathic injectables is safe and effective.

The EU legislator is asked to set up regulations that will guarantee the interests of doctors, patients and manufacturers of Homeopathic injectables for subcutaneous use.

1.2 Justification of the Position Paper

Since 1992, the date when Council Directive 92/73 EEC came into force, only oral and external application forms have been permitted within the simplified registration procedure.

The Commission Report on this Directive 1997 (COM 97/0362) suggested that “the scope of products subject to a simplified registration procedure should be increased”. European Parliament confirmed the strong need of this amendment (EP Resolution 227.183/end).

Nevertheless no amendment has been set up since then: As the 2001 Commission Review of the pharmaceutical legislation did not draft a proposal concerning this important aspect, it was taken up once again by the European Parliament in the first reading of the revision of Directive 2001/823 EC on 23. October 2002,; amendment 155 that states that any route of administration described in the European pharmacopoeia or in the absence thereof in a Pharmacopoeia currently used in a Member State can be permitted for simple registration.

Today legal and scientific experts in the field of Homeopathy want to improve the regulatory conditions of Homeopathic medicinal products in the course of this revision.

Up to now a plausible proof that Homeopathic ampoules for subcutaneous use represent safety problems compared to the oral application form has not been provided. Thus there is no sound reason to exclude the subcutaneous injections from the simplified registration procedure.

Prescribers and manufacturers in fact can demonstrate the safety of the subcutaneous way of administration on the base of pharmacovigilance data and therapeutic experience.

1.3 Historical Background

The history of the European simplified registration procedure with regard to Homeopathic injectables for subcutaneous use.

The first EU-Directive dealing with medicinal products was adopted in 1965. At that time the legislators were aware that the rules set up did not cover the needs of all existing and used medicinal products. Directive 75/319 EEC stated that this Directive and Directive 65/65 EEC are inadequate for a. o. Homeopathic medicinal products and „should consequently not be imposed in respect of such medicinal products“.

Only in 1992 Directive 92/73 EC established specific regulations for Homeopathic medicinal products. Medicinal products as used in Anthroposophic medicine prepared by a Homeopathic manufacturing method are to be treated in the same way.

Article 7 of Directive 92/73 established a simplified registration procedure for Homeopathic medicinal products that do not claim a therapeutic indication and are administered orally or externally.

These regulations are stated now in Art. 14 of the codified Directive 2001/83 EC.

The first “abbreviated” procedure, however, was introduced in Germany with the Drug Law in 1976. The quality, the safety and reference to the traditional clinical Homeopathic and Anthroposophic publications were the requirements for the application for these products and **all administration forms were included**. Since 1976 no safety problems caused by Homeopathic injections have occurred and a monograph was included into the official German Homeopathic Pharmacopoeia accordingly.

Nevertheless in the course of setting up EU regulations the various organisations involved in the legislation procedure, ignoring the long German safety record, and without any justifiable reason, restricted the European simplified registration to the oral and external dosage forms in a “sufficient degree of dilution”.

Only Homeopathic medicinal products for oral or external use in a sufficient degree of dilution were thought to fulfil the safety criteria for the simplified registration. Homeopathic ampoules were excluded with one stroke from the possibility of being registered by the simplified procedure: all ampoules (s.c.-, i.m.- and i.v.-application) for parenteral solution were thought to have some sort of risk and no benefit.

2.2 SCIENTIFIC ASPECTS

2.1 *The Quality of Homeopathic Parenteral Medicinal Products as used in Homeopathic and Anthroposophic Medicine*

Every parenteral Homeopathic medicinal product has to fully comply with the requirements of the official European Pharmacopoeia and/or the national official Homeopathic Pharmacopoeias of France or Germany. Homeopathic parenteral dosage forms are sterile medicinal products and have to fulfil all Pharmacopoeial quality aspects during the manufacturing process.

Any production site of injectables must comply completely with the respective requirements of Good Manufacturing Practice (GMP). Especially the technical equipment of production rooms for industrially manufactured injectables guarantees clean-room conditions. The filling of the ampoules has to take place under a laminar air-flow device in order to prevent any contamination of the sterile solutions.

At the end of the production process each ampoule has to pass a final sterilisation process which is monitored by the quality control unit. The up-to-date standard of industrially manufactured Homeopathic parenterals includes automatic testing on particulate matters in the solution as well as testing on fissures in the glass walls of the ampoules.

Each lot of a parenteral Homeopathic medicinal product has to pass the quality control unit and the microbiological test on sterility.

Furthermore all facilities manufacturing these sterile ampoules are inspected at regular intervals by national medicines inspectors under the PIC system.

These rigorous quality requirements and controls guarantee the quality and thus contribute to the safety of these medicinal products.

2.2 *The Safety of Homeopathic Parenteral Medicinal Products as used in Homeopathic and Anthroposophic Medicine*

The safety of parenteral dosage forms is mainly determined by the following parameters:

- the toxic risk of the respective active ingredient(s)
- the parenteral route of administration
- the sterility of the ampoules

The toxic risk of Homeopathic injectables is extremely low because the active ingredients are mostly in higher diluted or potentised form. In most cases the lowest dilution factor occurring in injectables is 1:10,000 or higher. A D4-potency corresponds to a 1:10,000 dilution. If an active ingredient has a high toxic risk the dilution factor is normally exceeding 1:10,000, e.g. nosodes, sarcodes, snake venoms or toxic heavy metals are used in 1:1,000,000 dilutions or a D6 potency at least. A toxic risk caused by the active ingredient(s) of a Homeopathic parenteral medicinal product does not exist because of the fact that generally any Homeopathic substance has to be diluted mostly 1:10,000 or higher when it is determined for a parenteral solution. The reason is that a parenteral solution has to be an aqueous solution; therefore the German Homeopathic Pharmacopoeia [Lit. 2] requires that for the last two potency steps (D-potentiation) the potentiation has to be made with water in order to reduce the alcohol content of the starting potency under 1% alcohol content. Normally the potentiation with water starts from the alcoholic D2-dilution because mother tinctures or D1-potencies often develop solubility problems when they become diluted with water. On the other side only a small number of homeopathically utilized substances bears still a real toxic risk if they are not higher diluted than 1:10,000, e. g. snake venoms, nosodes or poisonous heavy metals (mercury). For this specific category of substances detailed safety data are required by Authorities.

Adverse effects of Homeopathic Injectables

At the moment almost all Homeopathic injectables have been on the market since more than 30 years. During this time industry and authorities have monitored every Homeopathic medicinal product in a responsible way. The check of the data base of several Homeopathic and Anthroposophic manufacturers demonstrates that the rate of adverse effects is extremely low; within 10 years (1990- 2000) the number of reported adverse effects was far lower than 1 adverse effect per 5 Mio. injections [Lit.1]. As each pharmaceutical manufacturer is obliged by law to document every report on undesired adverse reactions and comment on each one by a medical expertise, the above mentioned figures clearly document that Homeopathic injectables have a very low rate of adverse effects.

2.3 The Therapeutic Relevance of Homeopathic Parenteral Medicinal Products as used in Homeopathic and Anthroposophic Medicine

The therapeutic relevance of Homeopathic parenteral medicinal products is documented for more than 100 years by Homeopathic literature and for 80 years by Anthroposophic literature. The subcutaneous application of the Homeopathic parenteral dosage form was first reported in 1867 [Lit. 3]. Since the beginning of the 20th century the parenteral dosage form became more and more important [Lit. 4] because far-sighted Homeopathic doctors noticed quite fast the advantages of this application form compared with the oral forms used initially, like globules, tablets and drops.

The quick response of the therapeutic effect, the possibility to apply the exact dosage of the medicinal product and the powerful effect on acute pain or inflammatory processes when administered locally was appreciated from the beginning. In case of nausea, this application form principally offers the only reliable way of application. Further salient aspects of the parenteral dosage form are the good patient compliance and the lack of viral or microbial risks because of the proven sterility of every parenteral preparation.

In the second half of the 20th century several authors reported the successful injection into acupuncture points or into Head's Zones (Segmental therapy) [Lit.5 and 6]. The injection into acupuncture points is a powerful treatment and allows a quick relief of pain or spasms located in an organ, region or tissue connected with a certain acupuncture point situated on a certain meridian.

Often a combination of a Homeopathic injectable with a neural therapeutic injection (procaine) is used which can result in amazingly fast effects of pain-relief or soothing spasms.

Based on their positive experiences using Homeopathic subcutaneous injections, either by the application of a single or a complex Homeopathic medication, practitioners consider that s.c.-injections of a Homeopathic medicinal product are reliable, safe and effective means of treatment.

Apart from the treatment of acute diseases, chronic conditions also respond well to the parenteral intervention as numerous publications demonstrate [Lit. 7, 8, 9, 10, 11, 12, 13]. In the last 15 years one can find several publications on the use of Homeopathic injectables e. g. for the treatment of chronic rheumatic diseases. A remarkable effectiveness of an Anthroposophic therapeutic approach by parenteral treatment of chronic rheumatic inflammatory processes was recently reported by G. Soldner and H. M. Stellmann [Lit. 14].

Controlled, double-blind clinical trials where Homeopathic medicinal products were tested against placebo or a well established allopathic medication have been carried out [Lit. 15].

The anthroposophic therapeutic approach builds up amongst others on the anthroposophic knowledge of man, which recognizes 3 functional levels of human physiology and pathophysiology. In order to address these functional levels in a specific and appropriate way, different dosage forms are needed [Lit. 16, 17, 18].

The nerve-sense-system is predominantly concentrated in the head and functionally serves conscious perception and thought. Breakdown processes and a lack of regenerative force dominate here. Dosage forms for external use primarily act through the nerve-sense system. In the metabolic-limb system, on the other hand, the constructive and regenerative forces are prevalent and form the basis for the will ability which, however, unfolds unconsciously. Oral and rectal dosage forms primarily act through the metabolic-limb system.

Between, in the rhythmic system, mediation between build-up and breakdown takes place through respiration and circulation - as a functional basis for feeling, which takes place semi-consciously. Parenteral dosage forms primarily act through the rhythmic system.

As can be seen, the parenteral dosage form (mainly subcutaneous application) is part of the anthroposophic therapeutic system. Therefore injectables are an indispensable dosage form within this therapeutic approach.

The reported results demonstrate that the Homeopathic medication is comparably efficient, has remarkable less side effects and saves costs. All this together indicates an advantage for the patient and the social insurance systems; because after long lasting usage of allopathic medication side effects can provoke their own adverse reactions, iatrogenic disease, which then has to be treated causing extra costs.

As a summary one can state that the Homeopathic injectables as used in Homeopathic and Anthroposophic medicine have a therapeutic relevance, are safe and cost saving.

2.4 The Subcutaneous Route of Administration

The subcutaneous way of parenteral administration is very widespread in Anthroposophic as well as in Homeopathic parenteral treatment and is showing hardly any side effects during decades of use [Lit. 1].

The evaluation of the pharmacovigilance data base of subcutaneously applied injectables of one Homeopathic and two Anthroposophic manufacturers demonstrates that the number of reported adverse reactions within a period of 10 years is even lower than 1:5,000,000, which means less than one adverse reaction per 5 Mio. subcutaneously applied single dosages.

<i>Manufacturer</i>	<i>Number of ampoules sold</i>	<i>Ampoule volume</i>	<i>Mode of administration</i>	<i>Number of adverse reactions</i>
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*List published in "DAZ" (German Pharmacists' Journal)
142.year, n° 29, 2002-07-18, p. 40-44*

98% of the few reported adverse reactions were minor in nature, such as "swelling or redness" and "temporary local pain"; only in extremely rare cases were severe allergic reactions or anaphylactoid reactions reported (<< 0,1 % of reports) [Lit. 1].

As a result one can conclude from these data that Homeopathic subcutaneously administered ampoules possess a very low risk potential which is equivalent to the low risk potential of the oral route of administration of Homeopathic medicinal products.

3. SOCIAL AND TRADITIONAL RELEVANCE

3.1 Statement by the ECH European Committee for Homeopathy.

The ECH is the European association for homeopathic medical doctors and other statutorily regulated health professionals in the field of homeopathy - veterinary surgeons, dentists, pharmacists, midwives. Its aim is to promote and defend the quality of the science of medical homeopathy.

The ECH unites 25 associations of medical doctors with specific training in homeopathy in 20 European countries, which means more than 85 % of all 12,000 qualified homeopathic doctors in Europe. In addition, most homeopathic veterinarians and dentists in the European Union are affiliated.

Besides the common oral route of administration, other dosage forms have always existed in homeopathic practice. One of these other dosage forms is homeopathic injections for subcutaneous use. These homeopathic injections have proven to be irreplaceable. No major adverse effects have ever been reported.

The ECH takes the position that homeopathic injections are a valuable instrument for the practice of homeopathy and that compliance with GMP and Pharmacopoeia requirements safeguards patients from any significant potential risk.

Dr. Ton Nicolai
President

The following associations are affiliated to the ECH:

Austria:

Ärztegesellschaft für Klassische Homöopathie
Kirchengasse 21 - 5020 Salzburg

Österreichische Gesellschaft für Homöopathische Medizin
Mariahilferstrasse 110 - 1070 Wien

Belgium:

Unio Homeopathica Belgica
Chaussée de Bruxelles, 132 - 1190 Bruxelles

Bulgaria:

Bulgarian Association of Homeopathic Physicians
10, Aleko Konstantinov Street - 1505 Sofia

Czech Republic:

Ceska Lekarska Homeopaticka Spolecnost
P.O.Box 25, Kafkova 19 - 160 00 Praha 6

Estonia:

Eesti Homöopaatia Ühing
Kreutzwaldi, 17-2 - 10124 Tallinn

France:

Syndicat National des Médecins Homéopathes Français
60, boulevard Latour Maubourg - 75007 Paris

Syndicat de la Médecine Homéopathique
72, avenue de Général Leclerc - 94700 Maisons-Alfort

Germany:

Deutscher Zentralverein Homöopathischer Ärzte
Am Hofgarten 5 - 53113 Bonn

Greece:

Hellenic Homeopathic Medical Society
Olenou 5 - 11362 Athens - Polygono

Hungary:

Magyar Homeopata Orvosi Egyesület
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Faculty of Homeopathy
15 Clerkenwell Close - London EC1R 0AA

3.2 Statement by ECPM

L'ECPM est une fédération qui regroupe la majorité des associations de médecine non conventionnelle en Europe (elle compte 43.000 membres, tous médecins). Son but est de défendre et de promouvoir le pluralisme des approches médicales et thérapeutiques.

Les médecins qui pratiquent ces thérapeutiques sont très attachés à la forme galénique injectable qu'ils considèrent comme indispensable.

Ils constatent quotidiennement (et en témoignent) l'efficacité irremplaçable de la forme injectable et son innocuité.

Souignons, qu'à notre connaissance, aucun incident n'a jamais été signalé par les Agences de pharmacovigilance.

Nos membres (et tous leurs patients) ne sauraient comprendre une interdiction ou une interruption dans la mise à disposition de la forme galénique injectable.

Docteur Robert Kempenich
Président

The ECPM represents the following European associations:

Austria:

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Switzerland:
Schweizerische Ärztengesellschaft für Erfahrungsmedizin (SAGEM)
Dr. A. Beck, Präsident
Kornhausplatz 7 - CH-3011 Bern

Schweizerischer Verein homöopathischer Ärzte (SVHA)
Dr. Clemens Dietrich
Rigistr. 5 - CH-5610 Wohlen

SOCIEDADE MEDICA TERAPIA NEURAL - P.
Gerente: Dr. Armando Gamas
St. Alban Anlage 45 - CH-4052 Basel

SOCIEDADE MEDICA PORTUGUESA
Regulacao e Terapia Neural segundo HUNEKE, Lda.
Director: Dr. Armando Gamas
St. Alban Anlage 45 - CH-4052 Basel

South Ukraina:
South Ukrainian Centre of Alternative Medecine
Odessa
cool@te.nct.ua

3.3 Statement by IVAA

The IVAA represents the Anthroposophical Medical Associations on the international level. In the European Union such professional associations of Anthroposophical Doctors exist in eleven Member States: Austria, Belgium, Denmark, Finland, France, Germany, Italy, the Netherlands, Spain, Sweden, and the United Kingdom.

All together 2.000 anthroposophical doctors need access to a wide range of therapeutic options, in particular anthroposophical medicinal products (both single substances and combination preparations). The parenteral forms of administration (especially injections) are an integral and indispensable part of our therapeutic approach.

The possible removal of these therapeutic options constitutes a very serious threat to our approach, and would amount to making it impossible for us to practise.

Dr. med. Giancarlo Buccheri
President

The IVAA represents the following European associations:

Austria:
Gesellschaft Anthroposophischer Ärzte Österreichs
Tilgnerstraße 3 - A - 1040 Wien

Belgium:
Belgische Vereniging van Anthroposofische Artsen
St. Denijslaan 311 - B - 9000 Gent

Denmark:
Dansk Selskab for Antroposofisk Medicin
c/o Inge Alsted Pedersen
Maglegårds Alle 110 st - DK - 2860 Søborg

Finland:
Antroposofisen lääketieteen yhdistyksen lääkäreiden työryhmä
c/o Reijo Kurppa
Muuralankumpu 1 D 1 - FIN - 02770 Espoo

France:
Secrétariat de Mercure Fédéral
1, rue Goethe - F - 67000 Strasbourg

Germany:
Gesellschaft Anthroposophischer Ärzte in Deutschland
Roggenstrasse 82 - D - 70794 Filderstadt

Italy:
Gruppo Medico Antroposofico Italiano
Via Privata Vasto 4 - I - 20121 Milano

The Netherlands:
Nederlandse Vereniging van Antroposofische Artsen
Secretariaat
Postbus 266 - NL - 3970 AG Driebergen

Sweden:
Läkarföreningen för Antroposofiskt Orienterad Medicin
Box 78 - S - 153 00 Järna

Spain:
Asociación de Médicos para la Medicina Antroposofica
c/Guiuzcoa 11,1 - E - 28020 Madrid

United Kingdom:
Anthroposophical Medical Association
Rudolf Steiner House
35 Park Road - GB - London NW1 6XT

3.4 Statement by the International Society of Homotoxicology

The International Society of Homotoxicology is an umbrella organisation comprising thirteen national bodies with 2,000 members world-wide.

The aim of the International Society of Homotoxicology is to promote the spread and establishment of Antihomotoxic therapy. Antihomotoxic medicine is a generalised therapy system with a high degree of individualisation. The advantages of such a therapy lie in its very flexibility. Bearing this in mind, practitioners need access to a wide range of therapeutics, in particular Homeopathic medicines (single and combination preparations). Though oral medication is doubtless very helpful, experience has shown that parenteral doses, in particular through subcutaneous application, bring the quickest and most wide-reaching results. In addition, subcutaneous application represents the least risky type of injection: a fact confirmed by the millions of amateurs (diabetics) who self-administer such injections on a daily basis.

Dr. Werner Frase
Vice President

The International Society of Homotoxicology represents the following European associations:

Belgium:

Belgische Vereniging voor Homotoxicologie en antihomotoxische Therapie v.z.w.
bzw. Association Belge d'Homotoxicologie et de Thérapie Antihomotoxique a.s.b.l.
P.B./B.P. 14 - 1730 Asse

Georgia:

Society of Biological Medicine and Homotoxicology
A. Kazbegi Ave. 33 - Tbilisi 38007

Greece:

Ellenike Etrairiaomotoxikolopas
Emm. Pappa 10 - 55134 Thessaloniki

Great Britain:

The Society for Homotoxicology & Anti-Homotoxic Therapy
c/o P.O. Box 217
Asford - Kent TN23 6 ZU

Italy:

Associazione Italiana di Omotossicologia
Via Durini 9 - 20121 Milano

Lithuania:

Homotoksikologijos ir Antihomotoksin_s Terapijos Asociacija
Partizan_g. 198-5 - 3041 Kaunas

Austria:

Österreichische Ärztesgesellschaft für Homotoxikologie
und Antihomotoxische Therapie
Postfach 64 - 1232 Wien

Poland:

Polskie Towarzystwo Homotoksykologii i Terapii Antyhomotoksyecznej
ul. Pulawska 52/38 - 02-559 Warszawa

Portugal:

Sociedade Médica Portuguesa de Homotoxicologia
Rua de Correiros 41 - 3Ro - Lisboa

Switzerland:

Schweizerische Gesellschaft für Homotoxikologie
und regulative Therapieverfahren
Paracelsus Klinik - 9062 Lustmühle b. St. Gallen

Slovakia:

Slovenská spoločnosť pre homotoxikológiu a
antihomotoxickú terapiu
Grösslingova 58 - 811 09 Bratislava

Spain:

Sociedad Española de Homotoxicología y Terapia Antihomotóxica
Apartado de correos 161 - 28770 Colmenar Viejo (Madrid)

Czech Republic:

Česká lékařská společnost pro homotoxikologii a antihomotoxickou terapii
Čestmírova 1 - 140 00 Praha 4

3.5 Statement by the International Society for Biological Medicine

The International Society for Biological Medicine is a specialist organisation of doctors, dentists, veterinarians and chemists. The purpose of the society is to safeguard and promote biological research and therapeutic methods, including medicinal and equipment-based therapies, hydrotherapy, acupuncture and balneotherapy.

At a global level, the society has organised numerous higher and further education events on the subject of naturopathy and related topics. The main focus of our international training courses is the application of different injection techniques using Homeopathic ampoule preparations. This includes naturopathic pain therapy (injecting pain areas, trigger points and interference fields), autohemotherapy, mesotherapy (connective tissue infiltration), biopuncture (injecting defined reaction and trigger points) and homeosiniatry (injecting acupuncture points), as well as standard injection and infusion therapy. Without the necessary ampoule preparations, all of these highly effective, tried and tested methods would no longer be possible.

For the naturopathic practice, the advantages of injection therapy are indispensable. The effect of such treatment is considerably quicker and greater, monitoring of the therapy is more exact, and patient compliance is undoubtedly better. In addition, such injections have been used for decades without risk. The idea of doing without Homeopathic ampoule preparations is unthinkable for doctors in the naturopathic sector; for the patients yet to be treated with these gentle yet effective remedies, it is an absolute disaster.

Dr. Klaus Küstermann
President

4. ECONOMIC ASPECTS

4.1 *Points concerning the Patients: The cost of Homeopathic Medicinal Products as used in Homeopathic and Anthroposophic Medicine*

During the last 5 years more than 450 millions of Homeopathic ampoules have been sold. These high sales figures can only be possible if on the one hand the medicinal product is highly effective and on the other hand the cost-benefit ratio is positive in comparison to allopathic medicinal products.

There is a very low incidence of adverse reactions, reducing subsequent costs charged to the patient or the health insurance.

There is an increasing number of patients with several chronic complaints, often requiring costly treatments. In these cases it is particularly important that economically reasonable therapies are given. Homeopathic and Anthroposophic treatments, with their low incidence of adverse reactions and pharmacological interactions, are likely to keep the costs as low as possible.

4.2 *Points concerning the Homeopathic/ Anthroposophic Industry: The vast Amount of small Batches required in Homeopathic and Anthroposophic Therapy creates high costs*

The Homeopathic and Anthroposophic industry produces a vast amount of Homeopathic medicinal products in small batches to fulfil the necessities of patients, as prescription occurs on a highly individual basis. To fulfil this duty belongs to the professional ethics of the Homeopathic and Anthroposophic industry.

The manufacturers understand without question that Good Manufacturing Practise and all other relevant quality assurance and control standards apply for all medicinal products, independently from their batch size or turnover.

For the Homeopathic and Anthroposophic industry a problem arises at this point:

The enormous amount of small batches of medicinal products makes production relatively expensive and non economic. On the other hand the economic agreement of western society bases on profitability of industrial work.

Because of the vast amount of small batches produced, the situation of the Homeopathic and Anthroposophic industry can be compared to the situation of the orphan drugs manufacturers from an economic point of view.

In both cases the manufacture and supply of the medicinal product cannot be recouped by large sales of specific products. Orphan drugs as well as small batches of Homeopathic medicinal products cannot be put at disposal to patients if the industry is not helped to overcome the particular economic difficulties connected to an orphan drug or to the huge amount of small batches of Homeopathic medicinal products. This applies particularly to the expensive dosage form "solution for injection" that requires expensive equipment, costly processing and highly specialised staff.

The task of legislation should be to enable the industry providing Homeopathic injectables to fulfil the expectations of patients and doctors requiring these medicinal products. Homeopathic injectables for subcutaneous use will become too expensive for the industry if these products cannot be registered by the simplified procedure.

4.3 Economic Consequences of the huge Amount of small Batches needed in Homeopathic and Anthroposophic Therapy for the Individual Patient:

Example of a company producing Homeopathic medicinal products in Europe:

Number of articles in the dosage form “solution for injection”: 3,717.

Number of units sold 2001: 716,227.

3,717 different articles is a huge amount which is typical for many Homeopathic and Anthroposophic pharmaceutical companies. This huge amount of different articles reflects the need for the individual therapy in Homeopathic and Anthroposophic medicine. To cover this demand is the ethical obligation of the Homeopathic and Anthroposophic industry. From the list (**data in bold letters**) it can be seen that 3,598 articles (2,563 + 877 + 158) are sold up to a maximum of 1000 units/ year.

Thus the relevant sales figures/article are extremely modest.

<i>Sales figures in categories</i>	<i>Sales figures summed</i>
up to 100 units sold: 2,563 articles	97,286
from 100 to 500 units sold: 877 articles	198,702
from 500 to 1,000 units sold: 158 articles	111,053
<i>from 1,000 to 2,000 units sold:</i> <i>69 articles</i>	<i>98,450</i>
<i>from 2,000 to 5,000 units sold:</i> <i>50 articles</i>	<i>148,298</i>
<i>from 5,000 to 10,000 units sold:</i> <i>8 articles</i>	<i>62,438</i>
Total	716,227

On the other hand, the number of units given to patients needing these medicinal products is 407,041 (97,286 + 198,702 + 111,053). **Thus there is a significant demand for these products from a therapeutic point of view.**

In order to be able to put at disposal all Homoeopathic medicinal products required by patients, the industry should not be burdened with excessive costs.

In particular it should be possible that Homeopathic medicinal products for subcutaneous administration benefit from the “simplified” registration procedure.

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