

Nosodes in Homeopathy: Significant and Safe

Position Paper

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1 DEFINITION

Nosodes are homeopathic preparations of organic material derived from inactivated disease products, cultures of micro organisms (e.g. bacteria, fungi and viruses) or parasites, infected or pathologically changed material or decomposition products from humans or animals, rendered safe during the homeopathic manufacturing process.

2 THE POSITION

In homeopathic prescribing nosodes play an indispensable role. This group of remedies has a tradition of more than two centuries. Results from clinical trials, post-marketing surveillance studies, and data collection in homeopathic practice show a long and safe track record. The manufacturing methods meet pharmacopoeia requirements and guarantee viral and microbiological safety. Therefore, patients, practitioners and professional organisations insist on the preservation of nosodes for homeopathic treatment.

Art 1 of the European Directive 2001/83/EC as amended by 2004/27/EC¹ defines a homeopathic medicinal product as:

“Any medicinal product prepared from substances called homeopathic stocks in accordance with a homeopathic manufacturing procedure described by the European Pharmacopoeia or, in the absence thereof, by the pharmacopoeias currently used officially in the Member States.”

National pharmacopoeias covering homeopathic medicinal products are the *German Homoeopathic Pharmacopoeia*² or the *French Pharmacopoeia*³.

3. INTRODUCTION

In Europe, homeopathy has a tradition of more than 200 years. Approx. 30,000 specialised medical doctors and around 100,000 practitioners practice homeopathic medicine. One out of four European families recognises homeopathic care as a form of therapy. Moreover, according to a study published in the Bulletin of the World Health Organization in 2000, more than 50% of complementary/alternative medicine (CAM) users are not ill, but evidently employ CAM in order to prevent illness. Although the true prevalence of the use of complementary and alternative medicine in the general population remains uncertain, available data suggests that complementary and alternative therapies are used frequently and increasingly.

In France, a 1996 study of 130,000 prescriptions suggested significant benefits and savings as a result of homeopathic treatment. This survey also noted that the number of paid sick leave days by patients under the care of homeopathic physicians were 3.5 times less than patients under the care of general practitioners. Although homeopathic medicines in France represent 5% of all medicines prescribed by physicians, they represent only 1,2 % of all drug reimbursements due to their lower cost per prescription. In all, these findings confirmed the results of the 1991 French Government Report, which in turn showed a significantly reduced cost from

homeopathic care versus conventional care. In all, these figures suggest further benefits and savings to the homeopathic approach to health care.

4. SIGNIFICANCE OF NOSODES IN HOMEOPATHY

The idea to use the infectious nature of certain diseases in a medical treatment was conceived, long before this was proven scientifically. Julian writes in the *Materia Medica of the Nosodes* that they were originally used as etiological medications, e.g. a diphtheria nosode for the treatment of diphtheria⁴. Soon, they were recognised as medications of the terrain, qualifying for patients with constitutional diseases.

Nosodes are applied according to homeopathic and isopathic principles world-wide for the treatment of acute as well as chronic diseases^{5 6}.

A 2005 survey conducted by ECH among their members, predominantly homeopathic doctors, veterinaries and dentists, revealed that 95% considered nosodes as important in their clinical practice.

A study by the VKHD (Verband Klassischer Homöopathen Deutschlands) in 2005 among 200 practitioners reported an average of 33% of patient cases where a nosode turned out of vital importance for a successful homeopathic treatment of chronic ailments.

5. ISOPATHY

One of the earliest innovations of homeopathy, even mentioned in the later editions of the Organon is isopathy or isotherapy. Coulter⁷ describes it as the element of homeopathic doctrine closest to Pasteur's interests, and notices that it was a part of Western medical culture long before its crystallisation in homeopathy. Wilhelm Lux, born in Silezia in 1776 and Professor of Veterinary Medicine at the University of Leipzig, observed that the technique of dilution and dynamisation of a contagious product would put such a product in a position to exert a therapeutic action on the disease resulting from the contagion⁸.

Isotherapy usually prescribes a remedy made from the supposed causative agents or products of a disease to a patient suffering that same disease. The method may be used to treat residual problems when an illness has been overcome earlier in life, problems following on vaccination, and also to reduce hereditary problems. Isopathy using nosodes should go hand in hand with carefully selected homeopathic treatment to cover the patient's presenting symptomatology.

6. EFFECTIVE IN VETERINARY MEDICINE

Also in veterinary medicine, nosodes have been demonstrated to be effective. Christopher Day, Veterinarian and former Chairman of the *International Association for Veterinary Homeopathy (IAVH)* has gained extensive experience with the use of nosodes in herds of food producing animals^{9 10}. Nosodes are successful in the treatment of severe and economically relevant health problems in these animals. Day: “Nosodes are an essential component of natural products for farm livestock. The European consumer is right in demanding an ever-decreasing reliance on conventional drug intake for food

animals. Natural products represent the only way forward to satisfy this demand in order to maintain or enhance the health of the animals. According to my experience, infectious diseases such as mastitis in many herds can only be treated using nosodes. The loss of nosodes for the homeopathic treatment approach would be a serious animal welfare issue."

7. VIRAL SAFETY

Since the source material of nosodes is potentially infectious, a perceived potential risk of infection is associated with their use.

However, according to the European Directive 2001/83/EC as amended, the requirement for the viral safety of nosodes is fulfilled by complying with the manufacturing methods specified in the German Homeopathic Pharmacopoeia or the French patented process of tyndallisation. The *Homeopathic Pharmacopoeia of the United States (HPUS)* considers both manufacturing methods as valid to guarantee the viral safety of nosodes and their safety for public health.

By applying the homeopathic potentisation procedures alone, the number of infectious particles decreases to zero in all potencies above 24X or 12C. At that level of dilution theoretically no molecule of the starting material can be present.

European Pharmacopoeia

According to the monograph *Homoeopathic Preparations* in the Ph. Eur. the donor has to follow the recommendations applicable to human blood donors and to donated blood (*Human Plasma for fractionation*), unless otherwise justified or authorised.

Situation in France

In France, the viral safety must be proved for each nosode. A validation of the manufacturing procedure must be carried out to demonstrate the non-infectiousness of the nosode donor. A serological examination of the donor similar to the processing of plasma and blood products is required.

The *French Homeopathic Pharmacopoeia (PPH)* does not contain a specification regulating the manufacture of nosodes. French homeopathic manufacturers have developed and patented a method for viral inactivation of homeopathic dilutions. It is characterised by heating an alcohol containing solution at a temperature ranging between 30 and 65 °C for one hour. The process is termed tyndallisation. The manufacturing methods do not require the sterilisation of the source material.

The origin of the source material has to be strictly controlled. Similar to the processing for blood and plasma products, a verification of the absence of infection with HIV 1 and 2, cytomegalovirus, HTLV 1 and 2, and hepatitis B and C viruses in the donors of human nosodes is required.

The study: "Evaluation of the viral safety level for the manufacturing process of homeopathic pharmaceutical products from animal origin" conducted by the Pasteur Institute in Paris demonstrated that the homeopathic potentisation procedure is reducing the concentration

of four selected model viruses by the factor 10^{-1} per potency. Therefore a certain endpoint exists, after which the concentration of potential pathogens is zero. Since the concentration of microbes may not exceed 10^{10} , one may assume that in homeopathic potencies higher than D10 or C5 no microbes are present anymore.

Situation in Germany

In Germany, all nosodes have to be manufactured in accordance with a uniform and validated procedure pursuant to the *German Homeopathic Pharmacopoeia (HAB)* [5]. All raw materials must be heated in saturated steam for 20 min at a core temperature of 133°C. Prior to its further processing, the starting material for nosodes must be shown to meet the requirements of the test "Sterility" (2.6.1) of the European Pharmacopoeia. This ensures that infective agents which may be present in the source material will be fully inactivated.

A spiking experiment with nosodes manufactured according to the HAB, demonstrated that this manufacturing method provides a final product free from any viruses. After the autoclaving process, the substance is extracted with 85% glycerol. Since 85% glycerol like 30% or 43% ethanol have antiviral and antimicrobial properties, the maceration in glycerol and subsequent potentisation in ethanol inhibits the growth of bacteria and viruses resulting in their inactivation. This process guarantees the microbiological safety of the subsequent homeopathic dilutions. Based on the current state of scientific knowledge for nosodes manufactured according to HAB specifications 43 and 44 with regard to the European Directive, the viral and antimicrobial safety is guaranteed in all potencies.

Using this method, the validation of the manufacturing method and proof of non-infectiousness of the nosode donor is not necessary.

8. STATEMENTS AND TESTIMONIALS

"For licensed health care providers using homeopathic medicinal products, nosodes are an indispensable part of homeopathy. Restriction of their availability would be an unacceptable curtailment of homeopathy" (Jacques Imberechts, former President of the *Liga Medicorum Homoeopathica Internationalis, LMHI*).

Dr. Ton Nicolai, MD Hom., President of the *European Committee for Homeopathy (ECH)*, fears that around 12,000 homeopathic medical doctors in Europe will be severely handicapped in their every-day practice if nosodes are not available.

For the *European Council of Doctors for Plurality (ECPM)* it is of major importance that medical therapies are not limited.

The *European Council for Classical Homeopathy (ECCH)* representing homeopathic practitioners: "It is essential that the availability of nosodes will be maintained for the benefit of the European citizens. Results from clinical trials, post-marketing surveillance studies, and data collection in homeopathic practice demonstrate

that nosodes are of no risk for patients whatsoever. All national and European authorities should, therefore, ensure that the existing legislation does not impose any restrictions on the use of these homeopathic medicinal products."

The statements of the health care providers are supported by patients' organisations. Sieglinde Schultz, MD Hom. and Chief Consultant of the German Organisation *Patients for Homeopathy (BPH)*, firmly requests politicians to ensure that nosodes will remain available without restrictions for the benefit of the patients.

George Vithoulkas, Professor of Homeopathy from Greece and laureate of the Alternative Nobel Prize: "A predisposition for chronic diseases can be influenced favourably by prescribing the indicated nosode¹¹."

Jonathan Shore, MD Hom. at the *Hahnemann Medical Clinic* in Berkeley, USA, writes that, in cases where no progress in healing occurs, the blockade can be overcome by prescribing a nosode. According to the understanding of the holistic treatment approach, chronic diseases are based on a predisposition blocking the healing process.

Anton Rohrer, MD Hom. and former Chairman of the *Austrian Society for Homeopathic Medicine (ÖGHM)*, confirms these observations: "The fact that well-chosen homeopathic medicinal products are not effective in a patient might be a symptom pointing to the need of a nosode. As a specific stimulus, nosodes can activate the healing power of the organism. Therefore, nosodes are also applied as reaction inducing medications¹². However, in most cases nosodes are used according to the Law of Similars with regard to their symptom picture."

According to the experience of David S. Riley, MD Hom. and Clinical Associate Professor at the University of New Mexico Medical School, and Medical Research Director of the *Integrative Medicine Institute* in Santa Fe, USA, nosodes are well established in every-day practice.

In future, it might be necessary to develop new nosodes especially for emerging chronic diseases. Karl-Heinz Gebhardt, MD Hom and Honorary President of the *German Association of Homeopathic Medical Doctors (DZVhÄ)* adds: "Nosodes produced according to the homeopathic manufacturing methods are clinically proven and represent an essential part of the treasure of homeopathic medicinal products. In most cases, the application of a nosode induces an immediate positive switch of the disease state."

The following organisations are supporting this position paper:

Bundesverband Patienten für Homöopathie (BPH)
Lange Strasse 47 - 37181 Hardegsen - Germany

Deutscher Zentralverein homöopathischer Ärzte (DZVhÄ)
Geschäftsstelle - Am Hofgarten 5 - 53113 Bonn - Germany

European Committee for Homeopathy (ECH)
Chaussée de Bruxelles 132, Box 1 - 1190 Brussels - Belgium

European Council for Classical Homeopathy (ECCH)
International Council for Classical Homeopathy (ICCH)
School House, Market Place
Kenninghall - Norfolk NR16 2AH - United Kingdom

European Council of Doctors for Plurality in Medicine (ECPM)
Ortenaustrasse 10 - 76199 Karlsruhe - Germany

Hahnemann Medical Clinic
828 San Pablo Ave - Albany, CA 49706 - USA

Homeopathic Pharmacopoeia Convention of the United States (HPCUS)
4974 Quebec Street NW - Washington, DC 20016 - USA

Integrative Medicine Institute
539 Harkle Road - Santa Fe, NM 87505 - USA

International Association for Veterinary Homeopathy (IAVH)
Sonnhaldenstrasse 4 - 8370 Sirnach - Switzerland

Internationale Medizinische Gesellschaft für Elektroakupunktur nach Voll e. V. Stuttgart (EAV)
Am Promenadenplatz 1 - 72250 Freudenstadt - Germany

Liga Medicorum Homeopathica Internationalis
General Secretary - Cuenca 87 Col. Alamos - 03400 Mexico D.F. - Mexico

Österreichische Gesellschaft für Homöopathische Medizin (ÖGHM)
Mariahilferstrasse 110 - 1070 Wien - Austria

Zentralverband der Ärzte für Naturheilverfahren e. V. (ZÄN)
Am Promenadenplatz 1 - 72250 Freudenstadt - Germany

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- ⁶ See also: Hahnemann, S. *Die chronischen Krankheiten: Ihre eigentümliche Natur und homöopathische Heilung*. 2. Auflage. Haug, Ulm (1956)
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- ¹² Rohrer, A. *Carcinosinum - Ein Mittel unserer Zeit*. *Documenta Homeopathica*. Band 11. Maudrich, Wien (1991)