ECH Symposium Barcelona
8 November 2013

16.00 to 17.30 (invited speakers)

16.00 – 16.15: Introduction and presentation by Dr Thomas Peinbauer, ECH President

16.15 – 16.35: Mme Marie-Anne Mouyart, HMPWG
The Justification of Homeopathic Use in the Context of the EU Legislation on Homeopathic Medicinal Products: A Challenge for the Future of Homeopathy and the Protection of the Public Health.

16.35 – 16.55: Dr Renzo Galassi, LMHI President
The LMHI Definition of the Homeopathic Remedy.

16.55 – 17.15: Mr Nand de Herdt, ECHAMP Past-President
The Homeopathic Remedies' Availability.

17.15 – 17.30: Mr Jack Hendrickx, Pharmacist
Remedy Bank – A Model to Ensure the Availability of Homeopathic Medicinal Products in Europe?

30 Minutes Break

18.00 to 19.30 (internal ECH speakers)

18.00 – 18.15: Dr Michel Van Wassenhoven, Past ECH Coordinator of the Research Subcommittee
Contribution of Basic and Clinical Research to the Registration of the Homeopathic Medicines.

18.15 – 18.30: Dr Jean Pierre Jansen, ECH Coordinator of the Provings Subcommittee
The ECH/LMHI Harmonization Project on Homeopathic Provings.

18.30 – 18.45: Dr Fruzsina Gábor, ECH Coordinator of the Pharmacy Subcommittee
ECH´s Contribution to HMPWG in 2013.

18.45 – 19.00: Mme Sato Liu, ECH Coordinator of the Patients/Users Subcommittee
The Patient´s View on the Availability of Homeopathic Medicinal Products.

19.00 – 19.30: Round table with all lecturers chaired by Dr Todd Hoover (HPUS)
Future Visions for Homeopathic Medicinal Products in Europe.

European Committee for Homeopathy

Marie-Anne MOUYART

Marie-Anne Mouyart, FAMHP, rapporteur of the HMPWG sub working group on Justification of Homeopathic Use.

The justification of homeopathic use in the context of the EU legislation on homeopathic medicinal products: a challenge for the future of homeopathy and the protection of the public health.

Taking into account the requirements of the Directive 2001/83/EC on medicinal products and in accordance with the criteria defined in the document "Points to consider on Justification of Homeopathic use" (HMPWG -Homeopathic Medicinal products Working Group- 2012)*, a first list of stocks for which the homeopathic use is considered justified has been adopted by the HMPWG after a public consultation on the HMA (Heads of Medicines Agencies) website.

One of the objectives of the HMPWG is to compile, as soon as possible, a list of justified stocks as comprehensive as possible.

Indeed due to the Principles of Homeopathy, in particular, the Similitude law, the future and quality of homeopathy is linked to the availability of a large number of well-defined stocks. Their quality must be guaranteed in order to produce safe homeopathic medicinal products.

We are faced to a big challenge which involves a lot of actors and needs the active collaboration of all of them (prescribers, pharmacists, industry, experts in different fields). All those actors and experts should be integrated in a large network including national and EU authorities.

The correct definition and characterization of the stocks and the justification of their Homeopathic use is a key element from which depends a lot of other aspects related to the quality and the safety assessment of the homeopathic medicinal products put on the market.

The HMPWG works thus also on the safety aspects and has already published documents related to the project FSD (First Safe Dilution) on the HMA website.

The outcome of the public consultation on the first list of justified stock is taken as an example to illustrate the context we are faced to.

*HMPWG documents are available on the HMA Website www.hma.eu/79.html

Dr Renzo Galassi

- *Since 1985, Dr. Renzo Galassi has been member of the Liga Medicorum Homoeopathica Internationalis (LMHI).*
- *1990: Degree of "Miembro Correspondiente" of Homeopatia de Mexico a.c.*
- *October 2001: Dr Galassi was appointed Italian National Vice President of the LMHI for a triennial mandate and was re-appointed for a further triennial mandate in 2004.*
- *He is one of the founder members of the F.I.A.M.O (Federazione Italiana delle Associazioni e dei Medici Omeopatici/ Italian Federation of the Homeopathic Doctors Associations).*
- *Since February 1999 he has been member of the non-conventional medicine committee as homeopathic expert doctor at the medical Association of Macerata.*
- *In 1989 along with few colleagues he created the Hahnemannian Homeopathic Academy of Marche Region which he still directs. He could thus promote triennial courses for doctors and annual courses for chemists.*
- *2007 he was appointed Prime General Secretary of the LMHI in Puebla, Mexico.*
- *2010 he was appointed Prime Vice President of the LMHI in Los Angeles, USA.*
- *In 2013 he was appointed PRESIDENT of the LMHI in Quito, Ecuador.*

The LMHI definition of the homeopathic remedy

The presentation will be about the document initiated by Michel Van Wassenhoven and Amarilys Cesar on Homeopathic remedies' definition. This document is, thanks to my initiative, under revision by our working groups as well as all the other statements of the LMHI. We are working to have better statements, with a more understandable language, with new addition of the new members of EC and members of the WGs.

Nand De Herdt

Nand De Herdt graduated in Pharmacy at the University of Leuven (Belgium) in 1972. He followed postgraduate educations in Homeopathy in Liège – School of Dr. Clercx and the French homoeopathic doctor Gérard Guéniot (1978-1979), Industrial Pharmacist in Basel and Stuttgart (1984-1985) and Marketing in Leuven (1995-1996).
He was dispensing chemist from 1972 until 1987. In 1988, he created the Weleda Company in Leuven - Belgium and stayed there as managing director until 1997. In 1998 Nand De Herdt moved to France to start the Central Registration Office of the Weleda Group. Since 1999 he is the European Affairs Officer for the Weleda Group.
In 1999, he was one of the co-founders of ECHAMP. Since the foundation he has been a member of the ECHAMP Board of Management. From 2004 until 2009, Nand De Herdt was the General Secretary of the Association. In April 2009, he was elected President of ECHAMP. He retired from all his professional functions in June 2013. Currently he still is active as independent consultant for EU CAM Affairs (Healthcare and Medicinal Products).

The homeopathic remedies' availability

In recent years, the availability of medicinal products has been in the centre of the discussions in the European Union. A first report on the topic was presented by the Heads of Medicines Agencies in November 2007. http://www.hma.eu/221.html
In 2010, the Health and Environment Committee (ENVI) of the European Parliament drafted a report on the differences in costs and access to pharmaceutical products in the EU.
http://www.europarl.europa.eu/meetdocs/2009_2014/documents/envi/dv/201/20110 5/20110523_pharma_summary_en.pdf

The European Commission has installed a so-called "Platform on access to medicines in Europe". This platform has published several reports.
http://ec.europa.eu/enterprise/sectors/healthcare/competitiveness/process_on_corpora te_responsibility/platform_access/index_en.htm#h2-1

And last September, the European Public Health Alliance (EPHA) has organised a conference in the European Parliament. http://www.epha.org/a/5809
Out of all these initiatives it became obvious that the regulatory environment and especially the lack of assessment capacities in the small and medium sized medicines agencies is one of the major reasons that equal availability and accessibility all over the EU is a major problem.

Homeopathic medicinal products have not yet been in the scope of these reports and conferences. This might change in a next report of the European Commission which is planned to be made public still in 2013.

In January 2012, the European Commission ordered a preliminary study on the availability of medicinal products for human use at the London based consultancy office Matrix Insight

The objectives of the study are:

- To collate data on the availability of medicinal products for human use across the EU.• To analyse the extent of unavailability problems, with a particular focus on small Member States.
- To identify the causes of the problem in the different Member States facing availability issues.
- To analyse how, and to what extent, recent changes to EU pharmaceutical legislation, and the modalities of application of regulatory requirements at EU or national level, have served to alleviate the problem.

Based on an 'informal suggestion' of Mr. John Dalli, the former European Commissioner for Health and Consumer Affairs, ECHAMP started producing such a study for homeopathic and anthroposophic medicinal products already in 2010.

With support of two independent surveys by PriceWaterhouseCoopers, ECHAMP investigated – in a very detailed way – the demand, availability, the European legislation and the regulatory environment. We found very interesting interconnections and four major deficits

The report summary concludes as follows:

The report represents a significant benchmark for analysis of this sector of the pharmaceutical industry in the EU. It is hoped it will initiate a discussion on the further actions needed to overcome the deficits of the enforcement of the implementation of rules for these products in the EU Member States, and, where needed, the disproportionate requirements and high administrative burden of the Community legislation. This is needed to guarantee not just the quality and safety but also the availability of homeopathic and anthroposophic medicinal products and to ensure freedom of choice for the tens of thousands of prescribers and many millions of users in the EU.

The full report has not been made public so far. It was sent to the European Commission and to Matrix Insight before they started the work on their report in the first half of 2012. We can almost be sure that the ECHAMP report will serve as a basis for the chapter on homeopathic medicinal products which will be part of the Matrix Insight and European Commission report. Before the end of 2013 we can be sure about this.

For the first time, an official European report will pay attention to the availability problems of homeopathic medicinal products in the European Union and in the Member States.

Jack Hendrickx

Jack Hendrickx studied pharmacy and industrial pharmacy at Antwerp University. Then his first job in homeopathic range was developing a new laboratory HOMEODEN in Ghent, Belgium (1980-1985) (later taken over by Heel to make Heel Belgium)
He started LABOTICS BVBA, construction company for homeopathic equipment, in 1984, and still running that company; (clients in 40 countries, 60 labs and 200 pharmacies)
He started LABOTICS SUPPLIES BVBA with my son Tom in 2008 (Distribution of granules/globules) and started RELMEDY BANK CVBA with Pha. De Marez in 2012.
Former co-ordinator of ECH subcommittee Pharmacy during 7 years.
Former president of Working group homeopathy with APB, Belgium
Former secretary and founding member of PHARAHOM VZW, Belgian homeopathic pharmacists.

Remedy Bank - A Model to ensure the Availability of Homeopathic Medicinal Products in Europe?

The ongoing crisis in the availability of homeopathic starting materials for dilution has finally a durable solution.

The independent production of these certified and GMP compliant raw materials is the goal of this REMEDY BANK cooperative corporation. Doctors, pharmacists and patients together are invited to take part in the capital of this exclusive source for certified and traceable homeopathic medicinal products answering to the European and other official pharmacopoeia's.

REMEDY BANK has a contract with a GAP certified botanical collection for the exclusive supply of more than 600 identified fresh plants used in homeopathy.

Starting in 2014 we will build up our catalogue, start stability studies hoping thus to extend shelf life of stocks, and work towards a solution for very difficult issues like nosodes and modern or new homeopathic medicines.

European Committee for Homeopathy

Dr Michel Van Wassenhoven

- *Medical doctor (Université Catholique de Louvain) 1974*
- *Electrocardiography (UCL) 1976 ; Specialist General Medicine (UCL) 1976*
- *Homeopathic MD (Ecole Belge d'Homéopathie, Bruxelles) 1979*
- *Founder and President of UNIO HOMEOPATHICA BELGICA 1986-2008*
- *Founder of ECH (1991), coordinator research sub-committee 1994-2012*
- *Belgian LMHI Vice President 1995-2007*
- *GIRI member (Groupe International de Recherche sur l'Infinitésimal) since 1996,*
- *GIRI Vice President since 1999*
- *President of the Belgian registration committee for homeopathic medicinal products (Service Public Fédéral Santé publique) since 2002.*
- *LMHI Secretary for Research 2007-2013*
- *Organiser of the 63th LMHI congress of the LMHI in 2008 in Belgium.*

Contribution of basic and clinical research to the registration of the homeopathic medicines

The registration or the authorization of a homeopathic medicine in Europe requires various types of scientific data, among them, in particular the requirements relative to the justification of the homeopathic use which are clearly specified in a published document on the website of the HMA (Head of Medicine Agencies). These requirements of scientific documentation of the homeopathic use are coming in addition to the requirements for quality control and safety which remain naturally essential and are the object of other criteria also published on this website. General information and guidelines are also available on the website Eudralex and on the website of the EMA.

For the clinical aspects, the necessary data are, according to their availability, the provings and the clinical verifications published case by case or into specific traditional homeopathic books called " material medica ". All other forms of clinical and fundamental research allowing to better understand the mode of action of the homeopathic remedy are useful for a simplified registration, and compulsory for the complete registration procedure ending in an AMM (marketing authorization) for this medicine. This presentation aims at presenting these various aspects of registration but also at underlining the last advances in basic research which should allow considering homoeopathy as being a part of the nano-medicine. This theme is considered in more and more publications in modern medicine but could have an implication (if confirmed) on the registration, GPP and delivery of the homeopathic medicines.

Dr Jean Pierre Jansen

Jean Pierre Jansen MD practices homeopathy, neural therapy and naturopathy in Groningen, The Netherlands, and has been coordinator of the ECH Subcommittee for Provings since 2008.

Dr Ashley Ross is head of the department of homeopathy at Durban University of Technology, where he practices homeopathy, and is coordinator of the LMHI Working Group for Provings.

Dr Ashley Ross on behalf of LMHI and Dr Jansen coordinate the harmonisation of proving guidelines of LMHI and ECH.

The ECH/LMHI Harmonization Project on Homeopathic Provings

Homeopathic provings are essential for the development of new materia medica knowledge. It was one of the first systematic research designs in medicine, and in as early as 1835 the first context for serious placebo research in medicine as well.

The revival of homeopathy in the 1970's came with a re-evaluation of quality aspects of provings. Bayr's inclusion criteria for symptoms are a landmark publication (1986) for this development. Since the early 1990's there is a trend to introduce concepts from conventional trials into the design of provings. Jeremy Sherr's publication (1994) inspired many, resulting in hundreds of provings since. In parallel, many new approaches to patient case analysis developed, which played a certain role in the way that provings are seen.

A systematic review (2007) of provings until 1995 found problems, when seen from a conventional scientific point of view. However, millions of cases are helped worldwide based on 200 years of provings. Furthermore, the maturation of a remedy's materia medica depends also on the pitfalls during the phase of clinical verification, which in the end is the yardstick for the validity of a proving. Therefore the need for improvements must be answered in these perspectives.

The ECH Subcommittee for Provings published its Proving Guidelines in 2004, taking first and for all into account two centuries of homeopathic theory and proving experience, and integrating both legal regulations and universally accepted documents on human experiments. A common misunderstanding became apparent, leading to the publication in 2005 of a position paper, concluding that provings are not phase I trials. Gradually the ECH guidelines have helped many stakeholders, including regulatory bodies, to gain insight into the purpose and homeopathic logic of provings.

Since 2011 the LMHI published two editions of its Guidelines for Provings, starting from the ECH Guidelines but with various major and minor differences. In a globalising context it seems logical that ECH and LMHI cooperate, so that all stakeholders can rely on a common document that is supported by the homeopathic profession that produces and uses the results of provings.

Therefore a harmonisation of ECH and LMHI guidelines for provings has been initiated, with the aim to publish the first harmonised edition during the LMHI Congress in Paris in July 2014.

During the presentation today a report about the results until now will be presented.

Dr Ashley Ross is head of the department of homeopathy at Durban University of Technology, where he practices homeopathy, and is coordinator of the LMHI Working Group for Provings.

Dr Ross, on behalf of LMHI, and Dr Jean Pierre Jansen coordinate the harmonisation of proving guidelines of LMHI and ECH.

Dr Todd Hoover

Dr. Todd Hoover is present at this Symposium as a representative from the Homeopathic Pharmacopeia of the United States (HPUS). Dr Hoover has been in homeopathic clinical practice and a Clinical Preceptor for Hahnemann Medical College for over 20 years. He is immediate past president of the American Institute of Homeopathy (AIH), current Trustee for the HPUS, Chair of the HPUS Provings committee, and current U.S. National Vice President for the LMHI. Dr Hoover has published research studies in both homeopathic and allopathic journals, and has presented lectures both in the U.S. and abroad on a wide array of homeopathic topics. Dr Hoover led the development of the recently published Proving Guidelines for the HPUS and brings the insights gained through that development to our meeting today.

Future Visions for Homeopathic Medicinal Products in Europe. Round table with all lecturers chaired by Dr Todd Hoover (HPUS)

Sato Liu

Sato Liu has been involved in the field of complementary medicine over 30 years; has studied homeopathy in some depth and has a working knowledge of anthroposophic medicine. Since the late 1980s she has worked as a patient advocate, lobbying both in UK and European parliaments for the availability of homeopathic and anthroposophic medicines and patients' rights to freedom of choice in medicine.

Sato currently works for the Friends of the Royal London Hospital for Integrated Medicine and campaigns for patient choice and access to complementary treatments on the National Health Service. She is also Secretary for the European Federation of Homeopathic Patients' Associations.

The Patient´s View on the Availability of Homeopathic Medicinal Products.