

# World Integrated Medicine Forum on the regulation of homoeopathic medicinal products: National and Global strategies

## Abstract

The first World Integrated Medicine Forum on the regulation of homoeopathic medicinal products included 50 delegates from 25 countries to discuss the current state of regulation of homoeopathic medicinal products (HMPs). The stakeholders in attendance included government officials, manufacturers, pharmacopoeia organisations, pharmacists, and healthcare providers worldwide. The Minister of Ayurveda, Yoga, Unani, Siddha and Homoeopathy from India, who is likely the only high ranking national official in the world specifically dedicated to oversight of traditional medicines including Homoeopathy, was the keynote speaker for the meeting. The core presentations delivered information on the country-to-country variance in regulatory requirements for homoeopathic medicine manufacture and marketing. Different speakers addressed the current pharmacopoeia structures in various countries, variance in premarket approval process, regulatory frameworks for homoeopathic medicines, labelling requirements, safety requirements, marketing approaches and good manufacturing practices. Debates focused on quality control testing, stability of intermediate stocks, shelf life of finished products, pre-market approval process and labelling and they shed light on regional differences in regulation. A lengthy discussion was held on the potential value of harmonisation of pharmacopoeias, manufacturing standards, safety evaluation and labelling. The group consensus was to meet again to pursue specific topics. Daily summaries of take-away points are provided at the end of each day's talk summaries. Much acclaim was won by the organisers for materialising this unique forum which proved to be an apt platform for rigorous discussions on lesser discussed, but very vital points such as regulations of HMPs, harmonisation of pharmacopoeias and linking industry and regulators' sectors for unified efforts for global development of Homoeopathy.

**Keywords:** Central Council for Research in Homoeopathy, Drug regulations, Export and import of homoeopathic medicines, Good manufacturing practices, Homoeopathic industry, Homoeopathic medicinal products, Homoeopathic pharmacopoeia, World Integrated Medicine Forum, Quality assurance

## FULL REPORT

In the presence of 50 delegates from 25 countries, the first World Integrated Medicine Forum on regulations of homoeopathic medicinal products (HMPs) was held from 23 to 24 February 2017 in New Delhi, India. The 2-day forum, organised by the Central Council for Research in Homoeopathy (CCRH) in collaboration with Dr. Robbert van Haselen, Director, World Integrated Medicine Forum, was inaugurated by the Honourable Minister of State Independent charge Sh. Shripad Yesso Naik, Ministry of Ayurveda, Yoga, Unani, Siddha and Homoeopathy (AYUSH), Government of India [Figure 1].

Sh. Naik praised the efforts of Council for arranging such a forum and stressed the importance of regulation of HMPs for the worldwide promotion of Homoeopathy. As demand for traditional and integrated medicine systems rises, legal access to high-quality HMPs can be assured

through a well-developed regulatory framework. He noted that the opinion leaders in India, including the late Mahatma Gandhi, had embraced Homoeopathy to a great extent. India currently has more than 2000 hospitals where homoeopathic medicines are used, 8000 outpatient centres for Homoeopathy, and more than 250,000 practitioners of homoeopathic medicine. Nearly 200 colleges provide training of homoeopathic doctors. Sh. Naik made an announcement that the Indian Government is in the process of building an All India Institute of Homoeopathy, which will be a full-scale hospital and training centre for Homoeopathy to be completed in approximately 5 years. As India is the country with the most homoeopathic medical providers, the Ministry of AYUSH supports all efforts to improve the quality and extent of homoeopathic care

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**Figure 1:** Inaugural ceremony in progress

delivery in India. In addition, India is actively promoting the improvement of international relations for cross-cultural support of AYUSH therapies.

The inaugural ceremony was also graced by Sh. Ajit M. Sharan, Secretary, Ministry of AYUSH, Sh. Anil K. Ganeriwala, Joint Secretary, Ministry of AYUSH, and Dr. S. S. Handa, Chairman, Scientific Body, Pharmacopoeia Commission for Indian Medicine and Homoeopathy (PCIMH). The highlight of the inaugural ceremony was signing of a Memorandum of Understanding (MoU) on cooperation in the field of homoeopathic medicine between the Homoeopathic Pharmacopoeia Convention of the United States (HPCUS) and Indian bodies –PCIMH and CCRH [Figure 2]. This agreement will enhance the dialogue and harmonisation of manufacturing and new drug evaluation practices between the two countries and will also be a benchmark for similar cooperation between countries. Such working relationships can help develop and harmonise homoeopathic pharmacopoeias and improve regulatory provisions for Homoeopathy worldwide. Also the new official website of CCRH was launched during the inaugural ceremony. This website at [www.ccrhinda.nic.in](http://www.ccrhinda.nic.in) has a wide range of research-based content and a more contemporary, user-friendly appeal [Figure 3].

The Forum had eight interactive sessions as follows: on 1st day.

1. Setting the scene: Practitioners' perspectives
2. Regulators' perspectives
3. Pharmaceutical industry perspectives
4. Regulatory status and outlook in various countries
5. Homoeopathic pharmacopoeias: Status in main countries
6. Monograph/regulatory requirements: Strategic aspects
7. Homoeopathic drug development, regulatory innovation
8. Enhancing synergies with traditional and conventional medicine systems.

Panel discussion were held on 2<sup>nd</sup> day.

This report presents a brief summary of each session [Figure 4]. The details of each speaker are presented in Table 1.



**Figure 2:** Signing and exchange of Memorandum of Understanding between Homoeopathic Pharmacopoeia Convention of the United States and Indian bodies Central Council for Research in Homoeopathy and Pharmacopoeia Commission for Indian Medicine and Homoeopathy

## 23<sup>RD</sup> FEBRUARY 2017

### Session 1: Setting the Scene: Practitioners' Perspectives

Chairs: Dr. V. K. Gupta, Chairman, Scientific Advisory Committee, Central Council for Research in Homoeopathy, India, and Dr. S. Soren, Advisor, Ministry of AYUSH, Govt. of India.

Dr. Hélène Renoux shared that 45,000 physicians are fully trained in Homoeopathy and provide care in the European countries. The European Committee for Homoeopathic includes both physicians and pharmacists. The perception of the current situation by the European medical doctors with an additional qualification in Homoeopathy is that there is a limitation of HMPs available to practitioners for daily practice. Furthermore, practitioners lack information on the authorisation of HMPs. Practitioners feel that there was a need for cooperation among big and small providers of HMPs to help the small pharmacists take over the magistral preparation work. In the Netherlands, a new registration programme began in 2002–2006. Due to the high price of registration, only about 20% of the medicines previously available were registered during this time period. In Italy, a very large increase in registration prices has caused disappearance of many homoeopathic medicines. In France, likewise, there is a decrease in 'smaller' or lesser used medicines due to cost of providing such medicines. In



Estonia, homeopathic medicines are not available in the pharmacies and are forbidden to be ordered by the internet. The primary barrier is very high registration fees. She suggested that the regulators should not only communicate with larger manufacturers when consulting on HMPs, but also representatives of patients, small pharmacies and medical doctors should be considered as important stakeholders.

Dr. Alok Pareek expressed the need to address the discrepancies arising out of non-standardisation of production of HMPs. The lack of confidence in certain production methods leads to a bias from the physician's side towards only choosing the scale of dynamisation he

trusts. Dr. Pareek also expressed the view that liberal rules for products not following the homeopathic cardinal principles of simplex or a thorough Hahnemannian proving and their labelling as 'homeopathic medicine' are causing deterioration in classical homeopathic practice. Standardisation is necessary in every aspect, right from proving to pharmacopoeias, manufacturing and dispensing. Liga Medicorum Homeopathica Internationalis (LMHI) is taking initiatives in bringing about this standardisation. The definition of 'homeopathic medicine' also needs to be unanimously decided for uniformity. Finally, he urged for coordination among all the stakeholders from producers to end users regarding use of HMPs.

While wrapping up the session, Dr. V. K. Gupta reported that the growth rate of homeopathic medicine sales in India is currently over 36%/year. He further said that over 600 million people use homeopathic medicine worldwide.

A discussion followed the first few talks regarding the issue of transportation of homeopathic medicines between countries. Many physicians and manufacturers have noted that various countries have stopped shipments of single and bulk products at the point of customs due to lack of documentation or lack of approval for externally manufactured drugs. A request was made to establish some international repository of information regarding various national requirements for the importation of homeopathic medicinal substances. In addition, there was a comment that perhaps a new formulary for combination products would help solve the conflagration that occurs when combination products are assumed to be the same as single remedies by regulators.



**Figure 3:** Launch of Central Council for Research in Homoeopathy new website: [www.ccrhindia.nic.in](http://www.ccrhindia.nic.in)



**Figure 4:** A glimpse of a few speakers of the forum

**Table 1: Speakers at the WIMF**

Name	Position
Hélène Renoux	President of the ECH, General Secretary of the SSH
Alok Pareek	International President-International Homoeopathic Medical Language-LMHI
Werner Knöss	Head of Division, Licensing 4-Complementary and Alternative Medicines and Traditional Medicines, Federal Institute for Drugs and Medical Devices, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Germany
An Lê	French National Agency for Medicines and Health Product Safety (ANSM)
Martin Ziak	Head of Division Complementary and Herbal Medicines at Swissmedic, Swiss Agency for Therapeutic Products, Bern, Switzerland
Cathie Vielle	Head, European Pharmacopoeia Department European Directorate for the Quality of Medicines
Raj K. Manchanda	Director General, Central Council for Research in Homoeopathy, Ministry of AYUSH
Irène Chetcuti	Attachee to the Director General, Boiron
Gunther Herr	Director Legal and Regulatory Affairs, Biologische Heilmittel Heel GmbH
Harald Josef Christian Orth	Director Pharmacy, Qualified Person DHU (Member of Dr. Willmar Schwabe group) Member of the German Homoeopathic Pharmacopoeia Committee, Member European Qualified Person Association, Member of the Society to Procure the Hahnemann House (Kothen, Germany), Member of Some Committees of the German Manufacturers Association (BPI/BAH, national or regional) Member APV (AGP Pharmazeutische Verfahrenstechnik)
Christiaan Mol	General Secretary, ECHAMP
John P. (Jay) Borneman	Chairman and CEO, Standard Homoeopathy Company (USA); President, HPCUS
Ashish Kumar	Managing Director, Schwabe India
Jack Hendrickx	Industrial Pharmacist, QP Remedy Bank
Irina Buryakova	Chief of Department of Traditional Medicine and Vice President, Russian Homoeopathic Association, Moscow, Russia
Nikolay Zamarenov	Professor-cum-chair, Homoeopathy and Electro-acupuncture Medicine Postgraduate University of State Federal Medico-Biological Agency Russia
Yelena Zyukina	Vice-President LMHI in Kazakhstan Vice-President AHML in Kazakhstan President Kazakh Homoeopathic Association
Ivan Kosalec	Associate Professor, Head of Microbiology Department, University of Zagreb, Faculty of Pharmacy and Biochemistry, Zagreb, Croatia
Diadelis Ramirez Figuerdeo	Senior Researcher Reviewer of Safety and Efficacy of Herbal Medicines and Synthetic products
Amarilis de Toledo Cesar	Doutoraem Saude Publica Pela Universidade de Sao Paulo Directora Tecnica H and N Hoeopatia - Farmacia HN Cristiano
Thanu Radha Malyauen	Principal Assistant Director, National Pharmaceutical Regulatory Agency, Malaysia
Torako Yui	Chairperson Japanese Homoeopathic Medical Association (JPHMA) Principal, CHhom Representative, Nippon TOYOUKE Natural Farming Co. Ltd.
To Ka Lun Aaron	President, Hong Kong Association of Homoeopathy President, Macau Association of Homoeopathy Course Homoeopathy (China); Medical Science Professor, UK Alternative Training (China)
Jianping Liu	Professor, Director, Centre for Evidence-Based Chinese Medicine, Beijing University of Chinese Medicine, China
Neil Gower	Council Member: Medicines Control Council of South Africa Senior Lecturer: University of Johannesburg, South Africa
An Le	French National Agency for Medicines and Health Product Safety (ANSM)
Rajeev Kr. Sharma	Director, Pharmacopoeia Commission for Indian Medicine and Homoeopathy, Ghaziabad
Amarilis de Toledo Cesar	Doutoraem Saude Publica pela Universidade de sao Paulo Directora Tecnica H and N Hoeopatia- Farmacia HN, Cristiano
Todd A. Hoover	Trustee on the Board of the HPCUS
Robbert Van Haselen	Director, World Integrated Medicine Forum, International Institute for Integrated Medicine, Research Consultant
D.C. Katoch	Adviser, Ministry of AYUSH, Govt. of India
Rajesh Shah	Director, Life Force Organizing Secretary, Global Homoeopathy Foundation
Harald John Hamre	Senior research scientist, IFAEMM at the Witten-Herdecke/University, Freiburg, Germany President and Scientific director, ESCAMP European Scientific Cooperative for Anthroposophic Medicinal Products
Thomas Breitzkreuz	Medical Director, Die Filderklinik, Stuttgart, Germany Chairman of Commission C, Federal Institute of Drugs and Medical Devices (BfArM) in Bonn, Germany Chairman of Hufelandgesellschaft, Berlin, Germany
Paulo Roberto Sousa Rocha	Ministry of Health of Brazil, Coordination of the National Policy of Integrative and Complementary Medicine in Health, Research Consultant for the Oswaldo Cruz Institution (FIOCRUZ)
Daniel Miele Amado	Ministry of Health of Brazil, Coordination of the National Policy of Integrative and Complementary Medicine, Research Consultant for the Oswaldo Cruz Institution (FIOCRUZ)
Madhur Gupta	Technical Officer (Pharmaceuticals), WHO Country office for India
Kim Sungchol	Regional Advisor for Traditional Medicine in WHO South-East Asia

ECH: European Committee for Homoeopathy; SSH: Societe Savante d'Homoeopathie; LMHI: Liga Medicorum Homoeopathica Internationalis; ECHAMP: European Coalition on Homoeopathic and Anthroposophic Medicinal Products; HPCUS: Homoeopathic Pharmacopoeia Convention of the United States; CHhom: College of Holistic Homoeopathy; IFAEMM: Institute for Applied Epistemology and Medical Methodology; BfArM: Bundesinstitut für Arzneimittel und Medizinprodukte; AYUSH: Ayurveda, Yoga, Unani, Siddha and Homoeopathy

## Session 2: Regulators' Perspectives

Chairs: Sh. Anil K. Ganeriwala, Joint Secretary, Ministry of AYUSH, Govt. of India, and Dr. Emiel van Galen, Head of Section for Homoeopathic and Herbal Medicines, Medicines Evaluation Board, The Netherlands.

Dr. Werner Knöss discussed the wide acceptance for Homoeopathy in Germany and that a substantial market consisting of both small- and medium-sized companies exists in the country. In Germany, initial regulation began in 1976 that various phytotherapies and homoeopathic medicines should be evaluated in a similar manner as drugs. The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte [BfArM]) is the body for legislation and regulatory framework in Germany. BfArM also does premarket evaluation with primary goal of establishing safety, efficacy and quality. Currently, 1235 licensed homoeopathic products, 1033 licensed anthroposophic products and over 3000 registered homoeopathic/anthroposophic products stand registered Germany. The complex regulatory framework within the Germany allows for two different types of marketing registration: (1) registration without indication claim and (2) marketing authorisation with a specific indication claim. However, the European Union (EU) process involves a similar step 1, but no step 2. HMPs, such as other medicines, require quality control and safety measures to protect public health, and their assessment must be based on specific expertise with due consideration to their particular characteristics while assessing these products for quality, safety and efficacy. Indications must be phrased in a way to connect it to homoeopathic use alone. Since ensuring protection of patients is of the utmost concern, risks, fraudulent products and the claims for use of the HMPs must be carefully evaluated. The European Pharmacopoeia currently contains 1038 monographs for homoeopathic preparations.

Dr. An Lê stated that HMPs had an official status in France since 1949, and the majority of these have been authorised through the codal 'visa' procedure in 1965. The methods for producing homoeopathic stocks were standardised and published in the French Pharmacopoeia since 1983. More than 30% of the French population currently uses homoeopathic medicines. Approximately 5000 general practitioners and 1300 acupuncturists specialised in Homoeopathy provide homoeopathic care in France. More than 32% of all general practitioners prescribe some homoeopathic medicines. Registered HMPs are reimbursed in France up to 30% of cost. Homoeopathic consultations are available in many hospitals in France. Similar to Germany, two marketing levels are available for registration of homoeopathic medicines. Simplified registration is possible for potencies between 2CH and 30CH. Marketing authorisations are used for mother tinctures, proprietary combination products and injectable forms. Ten new marketing applications have been granted between 2012 and 2016. For 2017, *Chelidonium* may shift from 4D to 7D because of pharmacovigilance reasons. Heavy metal

products (*Arsenic*, *Mercurious*, *Chromium*, etc.) are being reassessed for potential revision. Effectiveness is justified using bibliographical data and provings. A specific dossier as per the guidelines of International Council for Harmonisation is required for HMPs to assure safety and quality as well as to better justify their use. The homoeopathic pharmaceutical industry must be good manufacturing practice (GMP) compliant, which, in turn, calls for annual programmes inspection of manufacturing facilities.

Dr. Martin Ziak spoke through video link about the regulatory situation for HMPs in Switzerland. Their premarket authorisation process was established by a law in 2000 and updated in 2010. Currently, 21% of all medical products used in Switzerland are complementary medical products. A simplified registration process exists for homoeopathic products without a specific therapeutic indication (currently around 12,000 marketed products). Regulation is founded on a risk-based approach. Risk of harm is assumed to increase with therapeutic indication labelling. Therefore, documentation and cost of evaluation of homoeopathic products with indications are higher. Required clinical material and toxicology can be based on published bibliographical information alone. The homoeopathic and anthroposophic substance (HAS) list includes about 3500 HASs stating the allowable potency levels for the use in Switzerland. Based on the potency level, any new product for evaluation will need varying levels of documentation according to the risk as indicated in the HAS list. The specific risk evaluation is determined by the historic clinical use of a product, available toxicological data and planned clinical use for the product. Efforts are currently being made to simplify the authorisation process for new products.

Dr. Raj K. Manchanda described the regulation of HMPs in India. The regulatory framework is constructed for the Drugs and Cosmetics Act and Rules (D&C A/R) and Drug Controlling Authorities. State regulators are responsible for monitoring and enforcement. Today, there are about 13,000 graduates/year from homoeopathic colleges. Most people are not covered by health insurance in India. More than 80% of homoeopathic practitioners are working in private sector where insurance is not playing a large role. Looking at the marketplace overall, the cost of provider service is 85%, while medication cost is approximately 15%. Control of medicines is still under the conventional medicine legislation which makes Homoeopathy different than other AYUSH therapies. Central Drug Standards Control Organization is in-charge of setting standards for homoeopathic products in India. The homoeopathic-specific language of the D&C A/R and the recent amendments in the rules are making Homoeopathy more freely available for the public. Currently, there are 944 monographed substances in the pharmacopoeia. Quality of monograph varies significantly, and efforts are being directed to address inconsistencies. Specific guidelines for marketing authorisation of new products are currently being framed with input from committees of drug standardisation, drug proving, clinical verification,



homoeopathic pharmacopoeia and the sub-committee of Drug Technical Advisory Board. Efforts are underway to introduce an Intellectual Property Rights (IPRs) policy in Homoeopathy for the registration of new products, both single and complex preparations. This should encourage research investment. India is willing to join hands with the international community regarding both harmonisation and collaboration to ensure better regulatory environment for HMPs.

### Session 3: Pharmaceutical Industry Perspectives

Chairs: Dr. S. P. S. Bakshi, Chairman cum Managing Director (C.M.D) (Bakson Pvt. Ltd., and Former President, Central Council of Homoeopathy, Ministry of AYUSH, Govt. of India), and Dr. Robbert van Haselen (Director, World Integrated Medicine Forum).

Dr. Irène Chetcuti spoke about the challenges and opportunities for the development of good regulatory practices. Good regulatory practices should focus on legality, impartiality, consistency, proportionality, flexibility, effectiveness and efficiency of HMPs. A study done in 28 countries, involving three different products, revealed great variability in the length of the regulatory process. The review showed variation from less than a month up to 9 years. The review of the drug or update of use varied from <1 day to over 20 years. At present, the evaluation periods are too long for both regulators and companies. This is a particularly impactful issue since high numbers of products are required in the marketplace. The obvious variability of the regulatory practices may be due to a number of causes including lack of resources and overly burdensome procedures. Such regulatory hurdles may completely block the ability for a company to launch new products in that country. Automatic recognition of HMPs through bilateral or multilateral agreements should be promoted, which would eventually encourage regulatory convergence. Efforts should be made to include consideration of using conformity with a centralised monograph process in one country and to facilitate visibility, access, advertising and branding of HMPs. Practical solutions need to be worked out to avoid duplication of evaluations. This calls for enhanced work sharing within the Homoeopathy sector. Conformity to an official homoeopathic pharmacopoeia should be considered as adequate evaluation to approve for over-the-counter (OTC) use of a homoeopathic product. Marketing authorisations in one country could potentially be used as evidence to grant marketing authority in other countries through agreements between countries.

Dr. Gunther Herr stated that the definition of HMPs, as identified by WHO, is considered to be a helpful from a legal perspective. The definition is well phrased and clear, which can help with national legislation. In many countries, homoeopathic products are treated in similar ways as other medicinal products in terms of regulation. Attacks on marketing authorisations and registrations for HMPs often arise because they are not based on results of clinical trials. From the legal perspective, a simplified registration procedure is a

very helpful regulatory tool to ensure market access. Due to the specific characteristics of HMPs, conventional methods for clinical trials such as the generation of pharmacokinetic and pharmacodynamic data cannot be applied. On the other hand, if clinical evidence can be made available showing that the product works for specific indications, it should be possible to submit such evidence. 'Mixed marketing authorisations', which are based on a combination of product-specific data and bibliographic references, should be encouraged.

Dr. Harald Orth spoke about maintaining single homoeopathic medicines in the market in an era of increasing regulatory pressures: challenges and solutions. He provided historical context of Dr. Willmar Schwabe writing the sentinel work for homoeopathic pharmaceuticals, the 'Pharmacopoeia Homoeopathica Polyglottica'. In Germany, the rule of 1000 allows that different standards apply to those products with annual sales of less than 1000 units. This permits regulatory focus to remain upon those products with widest impact on the public, while still allowing reasonable access to the many less-utilised products that are produced by homoeopathic manufacturers. Dr. Orth recommended a centralised effort for indications/claims of medicines be completed by physicians who use these substances (perhaps through LMHI). There is a need to collect information at a global level on the claims and efficacy of various HMPs based on traditional or well-established use. Each medicine should mention the standardised dosage and first safe potency. A common nomenclature and a combined dossier valid in multiple countries will reduce costs and increase efficiency. He recommended a centralised effort for indications/claims of medicines be completed by physicians who use these substances. HMPs should be distributed in common public pharmacies or drug stores through official wholesalers.

Dr. Christiaan Mol presented information on the European Coalition on Homoeopathic and Anthroposophic Medicinal Products (ECHAMP) as advocates of an appropriate regulatory environment for HMPs products in the EU. Sustainable standards can be created by regulatory authorities. Borrowing from a sociological model, he used a tension triangle of state actors pulling against market actors pulling against patient actors. The tension between these three stakeholders should establish a balance within which sustainable standards can be developed. Insufficiency or excess by any of the stakeholders can result in failure of the standards. A recent survey of manufacturers in Europe revealed that a high percentage of homoeopathic products currently marketed have low or no profit margins. This raises concerns for either loss of products due to failure of profitability of homoeopathic products in the long run. Increasing regulatory cost pressures could continue to put pressure on this area of vulnerability. Both over- and under-regulation could be threats in their own ways; under-regulation is a threat to public health; over-regulation promotes black market and favours monopolist industry. He pointed out that the risk of failures can be minimised by producing sustainable standards based on

a well-balanced approach between different needs and tensions of the stakeholders.

Dr. J. P. Borneman presented a manufacturer's perspective of the regulatory framework for homeopathic drug products in the United States (US). He mentioned the unique role of the HPCUS as a nongovernmental organization in recognition of new medicines. The market of sales of homeopathic products in the US at this time is \$1.2 billion at retail. Manufacturers work within the HPCUS to ensure a stable supply of homeopathic medicines, quality and safety, as well as innovation and relatively low cost of products. Further improvements in the regulatory framework can be ensured through discretionary enforcement, more opportunities for working relationships with the Food and Drug Administration (FDA) and through greater clarity of state and local regulation.

Mr. Ashish Kumar presented the Indian industry perspective on the status of the Indian market and its unique features. In 2006, 40 million people used homeopathic treatment in India. This rose to an estimated 120 million in 2009 and is estimated to be 160 million in the current year. This huge number of users represents a great opportunity for producers of homeopathic products. There are currently over 400 manufacturers with GMP certification in India at this time. Homeopathy needs better scientific backing on the actions of high dilutions, including nano-particle research, biological evaluations, studies on gene expression and DNA sequencing. He pointed out that increased budget on publicity of the Homeopathy in electronic, print and internet media and endorsement by famous brand ambassadors for Homeopathy are required, but the market lacks funds for this. Allopathic companies traditionally advertise their OTC products, which help them mobilise patients. The Indian homeopathic drug industry has got to play a responsible role in this scenario by ensuring quality in product export, drug control and product development.

Mr. Jack Hendrickx explained that magistral and officinal preparations are composed inside a public pharmacy (or eventually a hospital pharmacy), whereas so-called registered drugs are always made by an authorised pharmaceutical manufacturer. The quality of the remedies preparation inside a pharmacy should be ensured. For instance, some countries have quality-driven handbooks for homeopathic preparation, and the validated equipment which is used in industry is also affordable and available for specialised pharmacies. The starting materials for each production should be quality controlled and evidence based. Homeopathy needs both magistral as well as industrially made remedies to keep a sufficient number of remedies and potencies available, as per the requirements of classical Homeopathy. He also emphasised on the need of European-wide, and worldwide, pragmatic harmonisation of guidelines for magistral and officinal preparations.

Overall, from the day's sessions, the main points that could be drawn about homeopathic pharmaceutical industry include as follows:

## Challenges

- Production of HMPs in terms of quality and safety
- GMP and good production practice compliance
- Pharmacovigilance for the assessment of benefit and risk
- Non-uniformity in the content of pharmacopoeia and monographs
- Compliance with good regulatory practices.

## Opportunities

- Inter-country work sharing for reducing financial implications
- Harmonisation of GMPs for uniformity
- Laying standards for universal drafting and use of pharmacopoeias
- Automatic recognition through bilateral or multilateral agreements
- Quality product export, quality control outsourcing, product development.

## Action points

- Facilitating visibility, access, advertising, branding of HMPs
- Finding practical solutions to avoid duplication of evaluations, enhance work sharing
- Encouraging regulatory convergence
- Promoting mixed marketing authorisations
- Better scientific backing on the actions of high dilutions.

## 24<sup>TH</sup> FEBRUARY 2017

### Session 4: Regulatory Status and Outlook in Various Countries

Chairs: Prof. Werner Knöss, Head, Department of Complementary and Alternative Medicines and Traditional Medicinal Products, Federal Institute for Drugs and Medical Devices, Germany, and Dr. Kim Sungchol, Regional Advisor of Traditional Medicine, WHO-SEARO, India.

Drs. Irina Buryakova and Nikolay Zamarenov from Russian Homeopathic Association, experts of working group on Homeopathy of Healthcare Committee of Government Duma of the Russian Federation, shared with the delegates the history of development of Homeopathy in Russia. No notification procedures have been adopted for homeopathic remedies which were permitted in the market for a long time. In 2015, it became mandatory that the homeopathic remedy must be produced from active pharmaceutical ingredient (pharmaceutical substance, introduced in an official pharmacopoeia). Russia does not have homeopathic pharmacopoeia of its own and no special rules were prescribed for registration, production and marketing of HMPs. In February 2017, a group of scientists and journalists published a document 'Memorandum N2', which referred to Homeopathy as a pseudoscience. However, the Ministry of Health did not support the opinion about prohibition of Homeopathy and

decided to appoint a special expert commission. They argued that Homoeopathy should be a complete doctrine in itself, with its own rules, and regulatory requirements meeting the conditions of Homoeopathy.

Dr. Yelena Zyukina, a practitioner from Kazakhstan, explained that drug control in her country, including of HMPs, is regulated by the Ministry of Health of the Republic of Kazakhstan, which, in turn, has a pharmacy committee and national centre of examination of medicines, medical devices and medical equipment. In Kazakhstan, there are 7849 registered drugs, 82 of which are homoeopathic drugs.

Dr. Ivan Kosalec explained that Croatia is the newest EU member. Croatia has very little tradition of use of Homoeopathy. In 2013, the medicinal products act created the pathway for market access to homoeopathic products. There are currently only four homoeopathic products on the market with indications. There are no new applications for simplified registration in the past 4 years. However, the practitioners are still using homoeopathic medicines in their offices without legal protection. This may be due to lack of homoeopathic pharmacy infrastructure in the country. They are currently trying to address this gap through education.

Dr. Diadelis Figueredo described the Cuban health system as universal and free. Drug surveillance network includes homoeopathic products, and of 868 essential drugs, 22 are registered HMPs. Currently, Cuba has 1465 specialists in Homoeopathy. Cuba must develop other vehicles such as globules and tablets for easy dispensing. HMP manufacturers must ensure safety, efficacy and quality. Lack of cooperation between manufacturers and doctors should be overcome, and more information should be circulated for the rational use of homoeopathic products.

Ms. Amarilys Cesar, a pharmacist from Brazil, informed that in her country, more than 90% of homoeopathic remedies are produced and dispensed in pharmacies. Since 2013, pharmacists have been allowed to prescribe OTC drugs, which include almost all the homoeopathic remedies. The current challenge is to prepare and educate pharmacists to help people with homoeopathic remedies.

Ms. Thanu Maiyauen from the Malaysian National Pharmaceutical Regulatory Agency explained that HMPs fall under the natural product category and their evaluation comes under abridged evaluation. Incomplete documentation, falsification of the data submitted and low levels of awareness of the current requirements are among the main challenges in Malaysia. To overcome these, the government has issued guidelines for homoeopathic products and has tried to collaborate with the local industry and the industry associations to further enhance the effectiveness of the current regulatory practices.

Dr. Torako Yui from Japan stated that homoeopathic products are under the control of Ministry of Health, Labour and Welfare, Government of Japan. Homoeopathy Japan Co. UK Ltd. is the

sole homoeopathic products manufacturer in Japan. She showed a short video to apprise the status of Homoeopathy in her country.

Mr. Aaron To from Hong Kong, China, explained that homoeopathic practice and HMPs are not regulated in Mainland China. He highlighted the problems faced by distributors, such as sale of HMPs carrying legal risks and sale of fake HMPs which are actually OTC traditional Chinese medicines (TCMs). The lack of a recognised status by the government prevents funding of any solutions. The quality of HMPs needs to be safeguarded by responsible distributors. He also expressed his concern about the dangerous use of potencies which are too high or too low by untrained persons who are not registered in professional associations. Attempts to register HMPs through the allopathic route involve high cost as it is charged per medical indication. He feels that regulation of homoeopathic providers should be done before regulation of HMPs. HMP distribution should be limited to trained professionals so that growth of the industry can be sustainable. HMP regulation should be distinct from the existing medicinal products policies as is the case for TCM. Single and complex remedies should be regulated differently.

Prof. Jianping Liu presented an academic's perspective on the development of Homoeopathy in Mainland China. Homoeopathy is not in the official health care service of Mainland China, but China does follow an integrative medicine model which constitutes a major part of health care system. Integrative medicine is taught through an established comprehensive education system at college for both undergraduate and graduate levels. Nearly, all western medicine hospitals have TCM (and/or acupuncture) departments. Challenges for the development of Homoeopathy in Mainland China are that opponents consider Homoeopathy a pseudoscience limited to placebo effects. Both patients and physicians know little about Homoeopathy and they lack an educational infrastructure and regulatory framework for Homoeopathy. Homoeopathy should be included as a part of integrative medicine since health care needs cannot be satisfied by one system of treatment alone.

Dr. Neil Gower from the Medicines Control Council of South Africa made a video presentation on the current regulatory status in South Africa. Currently, registration can be accomplished with historical use evidence for low-risk claims while a higher level of evidence is required for high-risk claims.

Brief updates on the status of Homoeopathy for two more countries were given by Ms. Andrea Szekely (Hungary) and Mr. Ashraf Hossain (Bangladesh). Ms. Szekely stated that Homoeopathy once enjoyed a strong use within the country, but under communist rule was banned. Most homoeopathic clinics were closed. Today, only medical doctors may practice Homoeopathy. There are currently about 300–400 physicians who use this therapy in private practice and about 3000 doctors who include Homoeopathy in their practice. Currently, about 20% of the population embraces the use of Homoeopathy, while another 20% actively opposes the use of this therapy



in the country. Mr. Hossain stated that in Bangladesh, there are 63 manufacturers in the country. Homoeopathic products are recognised as medicines per the WHO guidelines. Registration is required and depends upon a dossier which was implemented approximately 1 year ago. The current challenges include the importation of starting materials without certification of active ingredients. This makes registration of such medicines difficult.

### Session 5: Homoeopathic Pharmacopoeias: Status in Main Countries

Chairs: Dr. S. S. Handa, Chairman, Scientific Body, Pharmacopoeia Commission for Indian Medicine and Homoeopathy, India, and Dr. S P Singh, Former Advisor (Homoeopathy), Ministry of AYUSH, Govt. of India.

Prof. Dr. Werner Knöss explained that the regulatory approach in Germany aims at integration of homoeopathic and anthroposophic medicines into the regulatory framework for all medicines. The regulatory system also ensured the evaluation of medicinal products before access to the market and gives due consideration to particular characteristics in the assessment of quality, safety and efficacy. HMPs have been regulated in Germany since 1976 through the 'Medicinal Products Act', assuring quality and reproducibility. HMPs are characterised by the homoeopathic manufacturing procedure and specifications and raw materials and dosage forms have to comply with the requirements of the German Homoeopathic Pharmacopoeia or European Pharmacopoeia. He concluded by saying that the legislation and regulatory framework should consider the specific therapeutic approach of Homoeopathy and that HMPs require quality control and safety measures to protect public health.

Dr. An Lê explained that the French Pharmacopoeia was founded as early as 1818. It currently has 298 monographs for homoeopathic stocks. European regulation is strictly transposed in the French law (Code de la Santé Publique) for HMPs. A simplified registration process following the article 14 of the directive 2001/83/EC was amended by the directive 2004/27/EC. Stocks of HMPs are registered between 2CH to 30CH potencies. Apart from that, some complexes (mixtures) are also subject to registration, including oral or external administration. Marketing authorisation has likewise been amended and updated. This applies to mother tincture and specific proprietary formula, with complete indications, posology and precautions of use. Each HMP must fulfil the requirements of the common technical document format appropriate for HMPs. Quality and safety for HMPs are a prime concern for the government. Dr. Lê said that prioritisation for the assessment remains based on the risk and on shared pharmacovigilance cases. She concluded by sharing that new dossiers utilising the mutual recognition procedure in Europe should be prepared.

Dr. J. P. Borneman said that in the USA, homoeopathic drug products, since they are sold in interstate commerce, are subject

to Federal Law. In general, Congress (legislative branch) passes a law that is signed by the President (executive branch). It is up to the appropriate agency (reporting to the executive) to interpret the law and write regulations. Regulations can be further interpreted using 'guidance'. Guidance does not require notice and it can be changed by the agency (such as Food and Drug Administration) at any time. The most important law is the Food Drug and Cosmetic Act (as amended), 1938; Key Regulations are in Title 21 of the Code of Federal Regulations, Sections 210 and 211, and important guidance is in the FDA Compliance Policy Guide 400.400, 'Conditions Under Which Homeopathic Medicines May Be Marketed', 1990'. Dr. Borneman explained that in addition to the Federal Laws, The Homoeopathic Pharmacopoeia of the United States (HPUS) is recognised in the 1938 Act. Drugs monographed in the HPUS are considered 'official' and are deemed 'compendial'. Homoeopathic drug products that are not monographed in the HPUS may still be marketed, but FDA may inquire about indications. Further, since homoeopathic drugs are not subject to pre-market approval by the FDA, all HMPs are considered 'unapproved new drugs'. This legal definition does not currently affect free sale of the medicines. FDA is responsible for the enforcement of these particular regulations. Their scope includes routine and 'for-cause' facility audits that focus on GMP and homoeopathic manufacturing guideline compliance, as well as label and claims reviews that evaluate whether claims are appropriate for OTC (non-prescription) or prescription delivery. In addition, the FDA requires that the word 'homoeopathic' be prominently displayed in the principal display panel of the label.

Dr. Rajeev Kumar Sharma apprised the audience on the current status of Homoeopathic Pharmacopoeia of India (HPI). Ten volumes of HPI have been published. The Drugs and Cosmetic Act (1940) is followed for Quality Control of Homoeopathic Drugs. In total, 1112 monographs and standards for 263 finished products have been published in HPI.

Ms. Amarilys Cesar presented an overview of the status of the Brazilian Homoeopathic Pharmacopoeia. The current edition (3<sup>rd</sup>) was published in 2011, and it covered more than 100 monographs. The challenges for the Brazilian Homoeopathic Pharmacopoeia were to increase the number of monographs and to revise and improve the consistency of the current monographs; the current aims are to increase the number of monographs of homoeopathic medicines and to further harmonise the homoeopathic pharmacopoeia in Latin America. It is the only homoeopathic pharmacopoeia in South America and together with the Mexican Homeopathic Pharmacopoeia forms the main pharmacopoeias for Latin America.

### Session 6: Monograph and Regulatory Requirements: Strategic Aspects

Chairs: Dr. Thomas Breitkreuz, Chairman of Commission C, Federal Institute of Drugs and Medical Devices, Germany, and Dr. D. R. Lohar, Former Director, Homoeopathic Pharmacopoeia Laboratory, India.

Mr. Christiaan Mol elaborated on the strategic aspects to be considered with regard to quantification (assay, limit test) of homoeopathic preparations. He pointed out that governance will be easier with well-balanced standards that are considered as legitimate. Quality requirements for mother tinctures impact both public health and industries. Homoeopathic preparations are multi-substance mixtures that are defined by their manufacturing method. These preparations should be of high quality, and high-quality preparation. In turn, such quality preparations can only be obtained from a high-quality starting material. High quality shall mean that a starting material is a proper specimen of its species: only typical, characteristic substances or groups of substances should be relevant. While narrating the official approaches found in the EU, he explained that Germany, Netherlands and Italy accept dossiers without quantification of non-toxic substances, while France always requires dossier's quantification of non-toxic substances. As per the European Directorate for the Quality of Medicines (EDQM) guidelines for monographs on homoeopathic preparations (2013), an assay is included for the herbal drug and mother tincture, wherever appropriate. In looking at our medicines, we must consider efficacy, safety and quality. Regarding efficacy, our medicines must cause the systemic effect on the patient according to the treatment needs rather than a specific receptor–molecule interaction. Therefore, typical assays may not measure efficacy of the HMP in a valid way. He suggested that from the safety perspective, the determination of the upper limit of toxic substances (i.e., a limit test) can be rationally deduced. The position of ECHAMP is that quantity is less important than the presence of expected profile of the medicinal components. Thin-layer chromatography/high-performance thin-layer chromatography is therefore meaningful tool to detect the presence of meaningful compounds in a lot of cases. Semi-quantitative detection is also possible.

Dr. Todd A. Hoover and Dr. Robbert van Haselen presented on modernising monograph evaluation while respecting homoeopathic principles. They illustrated how the review of monographs by HPCUS is both a technical and clinical process. HPCUS is constantly updating its proving and clinical evidence standards to assure quality of monographs included in HPUS. Pre-market approval needs of allopathic and homoeopathic drugs are different: while the former depends on a single diagnostic indication, the latter presents a clinical composite picture. Therefore, the drug discovery and clinical verification approaches have to be different for the two. Information was presented on the current HPCUS and Vithoukas Compass joint research effort to investigate the validity of provings. In next 1–2 years, HPCUS will publish a new matrix of evidence requirements for monographs. An outline of this matrix and the accompanying monograph review process was presented. They recommended additional research and harmonisation of the monograph (new drug evaluation) process across pharmacopoeias.

Dr D. C. Katoch presented regulatory challenges and possibilities for HMPs. The key ingredients of safety, efficacy

and quality assurance were vital for growth of the homoeopathic market. Words such as 'substandard', 'spurious', 'misbranded' and 'adulterated drugs' need to be very cautiously and clearly defined to assure quality of HMPs. Similarly, sufficient emphasis should be laid on analysis/testing of quality of drugs and the methods adopted for it. Although the regulatory framework for Homoeopathy in India is well-defined, certain challenges need to be addressed. One of them is an inadequate representation of homoeopathic experts in the regulations-making body, namely, the Drug Technical Advisory Board. Enforcement of the legal provisions the manufacture and sale of homoeopathic medicines is inconsistent at this time because these authorities lie with each state. Homoeopathic medicines are very diverse in nature and their effects differ from other kinds of drugs. Furthermore, their micro, subtle detectability is an issue. Current scientific validation studies are not sufficient to satisfy the regulatory requirements for safety, efficacy and quality. He said that these issues need to be addressed, as well as the want of objective parameters of quality assessment, validation of manufacturing process, standard operating procedures for dilution, potentiation or dynamisation, provings, manufacturing and dispensing.

### Session 7: Homoeopathic Drug Development, Regulatory Innovation

Chairs: Prof. C. Nayak, Chairman, Homoeopathic Pharmacopoeia Committee, and Dr. Anil Khurana, Deputy Director General, Central Council for Research in Homoeopathy.

Dr. Rajesh Shah spoke on the challenges in new drug discovery (NDD) and his experiences in India related to his new drugs: *Capsaicin*, *hydroquinone*, *Hepatitis C Nosode* and *HIV Nosode*. He pointed out that the required regulations for NDD for Homoeopathy is not well-defined in the Drugs and Cosmetics Act, which, in turn, hampers drug research. He suggested that there should be a single window solution like NDD body, which should have decision-making powers and control. He further said that the IPRs opportunities in NDD should be tapped adequately.

Dr. Harald Hamre spoke on potentials for new regulatory models in integrative medicine. He mentioned that a large number of whole medical systems are used worldwide, such as Anthroposophic, Chinese, Homoeopathy, Ayurveda and Unani. As these systems employ large numbers of medicinal products, conducting clinical trials for each product and therapy is not feasible. He said that for these systems, efficacy documentation for market access often relies on bibliographic evidence, but there are other types of evidence apart from clinical trials and bibliographic data. He suggested that single cases and case series can also yield evidence for drug effects. He cited the example of propranolol side effect in the case of giant haemangioma used in the treatment in a child. The striking effect that occurred within a short time period in the absence of other treatment combined with some pharmacological plausibility led to a new indication approval by the FDA and a new use for this drug.

Furthermore, physicians' experiences with medicinal products can be systematically documented and critically assessed in a way that encourages the reporting of negative as well as positive patient responses to treatment (Vademecum project). While the validity of the information may be lower than that of clinical studies, it is higher than historical data from the literature. In addition, the project will tend to capture a richer and larger array of data than any clinical study could accomplish. Drug effects can also be assessed at the system level through system evaluation studies.

### Session 8: Enhancing Synergies with Traditional and Conventional Medicine Systems

Chairs: Dr. Eswara Das, Member, Scientific Advisory Committee, Central Council for Research in Homoeopathy, and Dr. K. S. Sethi, Deputy Advisor (Homoeopathy), Ministry of AYUSH, Govt. of India.

Dr. Thomas Breitreuz spoke on HMPs within the wider context of regulating traditional and integrated medical systems. He posed the question of whether the commonalities in these systems can generate mutual synergies. About one-third of all doctors are practicing integrative medicine in Germany, which reflects the emerging new paradigm of integrative medicine. They combine what is best for the patient from different traditional and complementary medicine (T&CM) systems and conventional medicine. Furthermore, this approach shares common questions and methodologies for the evaluation and research and promotes T&CM diversity and aims to promote cross-cultural appreciation and synergy. He suggested that global elaboration of integrative medicine should go hand in hand with global elaboration of an 'integrative regulation', which would share questions, scientific approaches, methodologies and global collaboration with integrative medicine. In such an integrative regulatory framework, safety is a predominant concern for common product registration. The approach here is substance-related and not related to the particular system of medicine. The particular system of medicine can help inform the overall approach to safety. Efforts might be considered to flow across disciplines, which share substances, as well as across national borders. This type of toxicology and pharmacovigilance approach would create synergistic advantages including potential cost savings. Effectiveness (and efficacy) however is best evaluated according to the particular system of medicine and therefore not as applicable to standard approaches across all disciplines.

Drs. Paulo Rocha and Daniel Amado next shared their Brazilian experience on the relation between national policies on integrative and complementary practices and the regulation of homoeopathic and other traditional and integrated medicine products. Their national health system has a National Policy of Integrative Medicine (PNPIC), which contemplates complex medicine systems and therapeutic resources, recognised as T&CM by WHO. Fourteen types of integrative therapies are included under this umbrella.

This policy created the real possibility of improvement in access of T&CM health services, previously restricted to private practice. Promotion of safe and effective practices in health assistance, prevention of diseases, health promotion, assistance and rehabilitation using T&CM are among the goals of this policy. Provision of T&CM services was on the rise in Brazil from 1070 in 2008 to 6090 in 2016. The availability of these services is 78% in primary care centres. The Brazilian national health system is also providing training on Homoeopathy to a large number of family physicians and trying to enhance access to homoeopathic medicines in the national health system. They told the audience that public health policies in Brazil adopt only those products and medicines that have been evaluated by ANVISA, the regulatory authority of Brazil. The rule (RDC 26/07) of the Brazilian regulatory framework deals with the registration of industrialised homoeopathic, anthroposophic and anti-homotoxic medicinal products, which is being proposed for further simplification of the regulatory process, thereby ensuring easier and quicker registration.

There are currently almost 80,000 pharmacies that sell homoeopathic medicines. Over 8000 pharmacists manufacture homoeopathic products in Brazil. Regulation affects compounding pharmacies which must comply with GMP. Single medicines within the potency limits (except injectable forms) and sold without indication are approvable by registration alone. Other products must go through the market licensing process. Changes to make the system more efficient and permit greater access to medicines are in process.

Drs. Madhur Gupta and Kim Sung Chol, representatives of the WHO, spoke next on the relation between the WHO traditional medicine strategy and the regulation of HMPs. Achieving universal health coverage, including financial risk protection, access to quality essential health-care services and access to safe, effective, quality and affordable essential medicines and vaccines for all, was one of the sustainable development goals of the WHO. Building a knowledge base for the management through policies, strengthening quality assurance, safety, proper use and effectiveness by regulation and promoting universal health coverage by integration are among the primary objectives of the WHO T&CM strategy. In this context, the WHO has also signed a MoU with the Ministry of AYUSH for cooperation on traditional medicine, 2016–2020. One of the goals of this MoU is the establishment of a network of international regulatory cooperation for T&CM practice. WHO's strategy on T&CM, 2014–2023 is a valuable tool for strengthening quality, safety and effectiveness. WHO has published a document on 'safety issues in the preparation of homoeopathic medicines', entailing details on the technical aspects of the production and manufacture of homoeopathic medicines that potentially have implications for their safety, relevance for establishing national quality standards and specifications for homoeopathic medicines, as well as for controlling their quality. All member states of WHO, partners and stakeholders have to take up strategic



actions to ensure quality and promotion of T&CM products. Safety or quality issues related to homoeopathic medicines such as authenticity of original drug substance and impurities need to be addressed. Regulations of HMPs need to focus on issues related to manufacturing and marketing and on consumer information. The world should try to leverage the existing strengths in India related to T&CM, such as ensuring good manufacturing and agricultural practices compliance, pharmacovigilance systems and competitive standards of Indian Pharmacopoeia Commission related to impurities. The current pharmacovigilance system for herbal medicines which includes participation by 130 countries might be adapted to include homoeopathic medicines as well in the future, they informed. Drs. Gupta and Chol concluded by sharing the vision and mission of South-East Asia Regulatory Network of WHO – ‘Healthy populations with timely access to affordable medical products of assured quality, safety and efficacy in all countries of the South-East Asia region and beyond,’ and ‘To develop and strengthen regulatory collaboration, convergence and reliance in the South-East Asia region over shared regulatory issues and challenges, that will build capacity and will enable national regulatory authorities to fulfil their mandates and better safeguard public health’.

These sessions were followed by a forum discussion on two topics:

1. Regulatory harmonisation and collaboration: Upsides, downsides, practical experiences. To what extent is it necessary?
2. The future of the regulation of HMPs; what are the strategic priorities? What is on the horizon?

The deliberations in this wrapping up session proved to be quite interactive and meaningful, with the panelists taking up for discussion most issues and concerns brought forth during the 2 days by the resource persons and delegates.

The highlights of the discussion and recurring concerns at the forum are given below:

- Across the world, access to less frequently used homoeopathic medicines appears to be decreasing due to higher regulatory requirements causing an imbalance to make availability of such medicines economically viable
- Mechanism of homoeopathic drug approval process varies from country to country
- The primary concern of regulatory authorities seems to be focussed on safety and quality of products first, with efficacy second. Because of lower evidentiary support for efficacy with many homoeopathic products, any perceived risk heavily influences the perceived risk benefit assessment by regulators. This imbalance needs to be addressed in a systematic way that is appropriate to the discipline of homoeopathic medicine
- A recurring theme from a number of countries is the regulatory effort to separate homoeopathic products into two distinct categories: those with low risk, generic, or absence

of medical claims and those with specific and higher risk claims for medical conditions. Regulation is thereby distinct for the two categories of products allowing those with lower risk to be more easily recognised, while those with higher risk must undergo a higher level of scientific scrutiny for safety and efficacy before market approval can be obtained

- A concern was raised numerous times about the issue of potency expiration dating in the intermediate stock solutions. The date of 5 years is used by many countries. However, due to the difficulty of measuring any meaningful or comprehensive surrogate markers for efficacy of the medicines, there does not seem to be a clear path to any alternative understanding of how to know if such solutions remain potent over time
- Concerns were raised over homoeopathic medicines prepared from ‘back’ potencies or older stock solutions that may or may not continue to be viable at this point in time. Some of these medicines cannot be replicated exactly which creates a problem for pharmacopoeia and regulatory management of such medicines around the globe.

### Recommendations

The recommendations that were made include:

- Harmonisation, or at least, collaboration, convergence and reliance on regulations of HMPs,
- Encouraging GMPs,
- Exchange of information for harmonisation and for collaborating for research on mapping the diversity in pharmacopoeia standards,
- Finding ways to evaluate and compare points of convergence and divergence across various countries, in terms of: HMP regulations, pharmacopoeias and industry standards,
- Exchange of MoUs among countries similar to the one signed between HPCUS and Indian bodies CCRH and PCIMH,
- All countries agreed to meet again to discuss further on specific areas related to drug regulations and harmonisation of pharmacopoeias.

Much acclaim was won by the organisers for materialising this unique forum which proved to be an apt platform for rigorous discussions on lesser discussed but very vital points such as regulations of HMPs, harmonisation of pharmacopoeias and linking industry and regulators’ sectors for unified efforts for global development of Homoeopathy [Figure 5].

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**Figure 5:** Multi-national delegation at the forum

Noida, and Dr. Devki Pant, Research Officer (Phg.), HPL for contributing their reports on various sessions of the forum.

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### Conflicts of interest

None declared.

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