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DRUG STANDARDISATION & HOMOEOPATHIC PHARMACEUTICAL INDUSTRY

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As students we were often asked "What action one can take if selected or indicated remedy fails?" The answer invariably used to be " Selection is incorrect and case needs to be retaken to find a correct remedy". We never even imagined at that point of time that the remedy selected could be substandard or prepared from unidentified source. This I am talking about 40 years ago and in fact we never doubted the credentials of the homoeopathic pharmacist. But all the same I would like to tell you a very interesting story told by celebrated Dr. Schmidt of Geneva when he was at the Homoeopathic College at Bombay in 1960. He placed an order of homoeopathic medicines with a renowned pharmacist of US. The list included names of genuine homoeopathic medicines, few generic names of the plants and animals those were not used in Homoeopathy, and some imaginary and fictitious combinations of names. He said that to his greatest surprise he received all the medicines in all the various potencies asked for. Since then at least my impressions of the pharmacists has changed.

When I joined the Ministry as Research Officer in the Homoeopathic Pharmacopoeia and later at the Central Council for Research in Indian Medicine and Homoeopathy (CCRIMH) in 1970, I was constantly working out in my mind on a pilot project to standardise homoeopathic medicines. At the meeting of the Scientific Advisory Committee of CCRIMH at Kottayam in Kerala I proposed this concept of mine. This was strongly supported by Dr. R.B. Arora the then Head of the Department of Pharmacology at the AIIMS and Dr. (Smt.) Basu of the Dept. of Chemistry. Parameters were drawn to standardise the medicine. The first drug that we undertook was *Aconite napellus.* Ayurvedic units of the CCRIMH helped us to procure authenticated samples of *A.nap.*, and we carried out its microscopic and macroscopic evaluation. Mother tincture was prepared according to the standard method mentioned in United States Homoeopathic Pharmacopoeia (HPUS) and its analysis was done in the chemistry lab of the AIIMS. We compared the available samples of the same drugs from the market and analysed the same. The results were very disturbing. Our desire to go ahead with the project was therefore got renewed We decided to start this as a regular project under CCRIMH. In 1972, I moved to Central Research Institute, Calcutta where I had more scope and better staff and facility, and started regularly working on the standardisation project. Many indigenous plants were taken up for standardisation. Research papers were published in National Journals. Armed with this success we started more units under the control of CCRIMH at Bombay, Calcutta, Danapur(Patna) and Hyderabad. The same concept later created the Homoeopathic Pharmacopoeia Laboratory at Ghaziabad. I am a contented person today that the seed sown has turned into a large tree. Thanks to the staff and the personnel of that organisation.

The ideal of any Homoeopathic Pharmacopoeia is to give to the manufacturer specific directions with respect to *collection, identification, preparation and preservation of the source material and finished product*; and ensure to the physician the availability of a standard drug material.

Effects of the homoeopathic drugs are *qualitative and not quantitative.* Hahnemannian provings are the one means of obtaining these qualitative effects. In order to obtain reproducible effects at all times source material of uniform quality is essential. When we study relevant homoeopathic literature critically, we do find discrepancies.

The morphological characters which can be easily distinguished and those characters which can differentiate the source amongst the various species or varieties of the same family should be categorically mentioned that no confusion results while collecting the material.

Though morphologically correct the different developmental stages of the plant can alter the constituents of a particular specimen and therefore efforts should be made to fix the developmental stage as one of the parameters for collection. The variations in the sources may look apparently very trivial, but they indicate a lack of serious scientific thinking. *Standardisation of source material is therefore very imperative.*

It may be quite possible that the medicinal properties of different parts of the plant substance may vary in quantity

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with the result that the reactive responses which form the basis of our materia medica, may bring out serious qualitative discrepancies. In order to retain the original spirit and the effects of the proving the identity of the original substance used in the proving will have to be established. *If there is any doubt in coming to conclusion, it will be necessary to conduct a fresh proving, after standardising the drug substance.*

Hahnemann classified the drug material into nine classes. We are all aware of that classification. But while critically reviewing through that we find that the classification sounds very arbitrary and without logic. We fail to understand the various values of the drug strength mentioned by Hahnemann.

In order to overcome this situation mother tinctures are now being prepared in accordance with the modern method described in HPUS. How far these mother tinctures compare with these preparations employed in their original proving needs verification. The mosaic of the various constituents is important and is controlled by the genetic make up of the species concerned. *This mosaic is responsible for the quality of its action.*

Hahnemann advocated maceration as a method of preparation of mother tinctures. The American Pharmacopoeia suggests percolation method. Since the quality of the mother tincture in terms of its constituents hardly appears to alter, the method may be accepted. It is certainly a quicker method of procuring the mother tincture. This method is more useful particularly when the drug substance is dry, gummy and mucilagenous.

Hahnemann has given clear instructions with respect to the preparation of potency upto 30c. HPUS directs that, to avoid any confusion only one vial marked with two markings should be used, the lower one for the drug substance and the upper one for the vehicle. These are one bottle potencies. Jenichen, Korsikoff, Skinner, and the manufacturing chemists of the modern times have adopted modified techniques contrary to the instructions of Hahnemann. All these high potencies are now manufactured through automatic machines. Unfortunately the exact mode of preparation of these high potencies is not known. Nor there are any directions governing their preparations mentioned in the pharmacopoeia. It only appears that 1M, 10M, 50M, CM, are mere denominations without any exact meaning. Today we see that some of the multinational manufacturing units employ automatic machines. In order to achieve the standard of the finished product it will be desirable to describe the exact working and functioning of these machines. All the manufacturing units then should use these standardised gadgets. Already there is a lot of mysticism present with potentization, let us not add to that confusion. It is high time that the industry should make the necessary efforts to establish their scientificity in terms of methodology. They should establish uniform and transparent methodology to make them truly internationally acceptable. The manufacturing houses are obliged to the physicians and the patients alike and should not betray their faith.

The review of the available literature on the pharmaceutical aspect of Homoeopathy shows clearly that a lot is yet to be understood and a lot is yet to be done to make the scientificity of Homoeopathy forthright.

Hahnemann's original procedure should be followed as far as possible. If this is not possible the new method of drug preparation should be standardised and reproving conducted.

Wherever possible analytical tests suggested for confirmation should be simple and easily reproducible without involvement of much cost for the manufacturer.

While maintaining the standards of the drug substance which is very essential, methods devised should be simple wherever possible and reproducible, But wherever simple method may not be possible then recourse to elaborate method may be used. Cost need not sacrifice the scientificity of the end product.

Many have question to ask. "How do you standardise the potency".? My answer to this is till we have sophisticated and extremely sensitive instruments to detect the potency variation in a given sample we have to depend on the manufacturer who has a standard method used for collection, identification, preparation and standardisation for its preparation of mother tincture and he uses the standard method of potentization then the potency thus produced should be standard. You will see how important is the role of a manufacturer. The Homoeopathic Pharmacopoeia Committee is alive to this situation and is making all efforts too bring the standards while taking into confidence the various manufacturing units. There is likelihood that all decisions of HPI may not be suiting the thinking of some of the units but these decisions are taken in the best interest of the profession. HPI for that matter is open to discussions.