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GMP AND HOMOEOPATHIC PHARMACEUTICAL INDUSTRY

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I compliment the Central Council for Research in Homoeopathy on organizing this learned seminar. Regular interaction between the Council and the industry is a necessary prerequisite for giving impetus to research in this field and to carry the fruits of research from the laboratory to the clinic.

The subject on which I have been invited to speak. namely "GMP and Homoeopathic Pharmaceutical Industry" is especially important. If GMP is important for allopathic industry, it is doubly important for homoeopathic industry, as the medicines that we use is in very small quantities which requires by definition, PURITY and PERFECT measurement of qualities.

We have earlier coined slogan of our products being, PURE and PERFECT. This was based on the following quote of Dr. Hahnemann, the father of Homoeopathy. *"A dedicated physician can only be sure about the healing properties of a drug when it is made as Pure and as Perfect as possible".*

The concept of GMP was mooted around 1967 in the World Health Assembly which has since become WHO - World Health Organisation. The context was widespread instances of trading of sub-standard drugs in the international market. It was also realized, and we see now, that testing of the finished product is not enough to ensure the quality of drugs. GMP - covering the entire manufacturing process - has therefore become an integral part of what is known as WHO's Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce.

Many changes have taken place since then. Amongst other changes, the latest version takes account of the ISO-9000 series Quality Systems standards set up by the International Standards Organisation (ISO).

In our country, GMP guidelines were given statutory status for the allopathic industry in 1988 in Schedule M of the Drugs and Cosmeties Act. Statutory guidelines have also been introduced for Ayurveda in June, 2000. But, for Homoeopathy, no guidelines have been laid down yet. Some principles are set out for Homoeopathy in Schedule M-1 of the Act, relating to licencing of Industrial units. But they are by no means comprehensive. In my view the guidelines for the allopathic industry are appropriate for adaptation for homoeopathic industry with certain modifications.

The purpose of the GMP initiative is to ensure, inter-alia, the following :

a) Better product specifications and quality.
b) Clear enunciation of production operations and quality systems.
c) Proper arrangements for sourcing of raw materials of requisite specification, their processing and costing of the finished product, each batch of it, according to well defined procedures.
d) Proper arrangement for storage of the finished product at the plant, in transit, and all through the distribution channel to maintain quality throughout the product's shelf life.
e) Validation, and periodical audit of quality systems, and their application.

As stated earlier, schedule M under the Rules framed under the Drugs & Cosmetics Act, 1940 had specified the requirements for meeting the prescribed standards of GMP. There is confusion whether this is applicable also for homoeopathic industry. The confusion will be obvious from our own experience. We had applied for and obtained a GMP Certificate from the Drug Authorities of Government of Rajasthan. However, when we approached the U.P. Drug Authorities, they would not commit in respect of our factory and manufacturing practices under Schedule M, as according to them the Schedule M is applicable only to allopathic industry.

It is understood that GMP standards for homoeopathic industry are now under preparation. I would like to request the Central Government to have the rules approved at the earliest. In the meantime, pending approval of the draft rules for GMP in homoeopathic industry, perhaps the Central Government could direct the state Drug Authorities

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to inspect and if satisfied, issue a GMP Certificate based on Schedule M of Drug rules.

I would like to mention that almost all the countries who may be interested in importing homoeopathic remedies manufactured in India, insist on GMP Certification. Inability to produce such a GMP Certificate has been a major bottleneck for us in finding export market for our excellent quality products.

According to us, GMP is not an option in Homoeopathy. It is a pre-condition for entry into the business of manufacturing homoeopathic remedies and staying in it. If India hopes to be a global player in the field of Homoeopathy, establishment of GMP in homoeopathic manufacturing practices is a MUST. Adherence to good manufacturing practice is even more critical for Homoeopathy than for allopathy. This is so, because there is "NO GO - NO GO" gauge which can test a homoeopathic remedy, its efficacy can be assured only by the punctiliousness of its manufacture.

In a Mother Tincture, we can test the identity of the herb and the quantum of dissolved solids. But, how do we test for therapeutic efficacy of the medicine, which depends on the maturity and freshness of the herb, and the way it has been macerated and processed and handled.

How do we test the quality of Dilutions? According to Avogadro's principle, above the potency 30 no trace of the medicine survives in the liquid; only dynamic memory of the medicine remains. It heals, but it defies detection. The same applies to high potency tablets and other formulations. The upshot is that efficacy of homoeopathic medicines is dependent entirely on the integrity of the manufacturer and the manufacturing process. GMP will instill that integrity. It is needed to replace seductive packaging and cheap pricing as the mainstay of Homoeopathy., Therein lies its criticality.

The manufacture of homoeopathic products in India started quite some time ago. The companies were small and they were not particularly conscious of good manufacturing practices. Neither, the Central Government nor the State Governments insisted on the quality of manufacturing practices before issuance and renewal of Drug Licences for manufacture of homoeopathic products. I am sorry to state that in many cases, such practices are sadly lacking. There are exceptions like HAPCO of Kolkata who voluntarily did their best to maintain good practices in their factory. Now that SBL, in collaboration with Boiron of France and Willmar Schwabe, a well known German company, have come to India, everybody can see what GMP standards mean and why it is so crucial for manufacture of effective homoeopathic drugs.

For establishing GMP there is considerable investment involved in-

- Treatment water,
- Use of non-contaminating vessels made of standard stainless steel and other equipment connected with the manufacture;
- Minimum testing equipment to distinguish good quality raw material from bad ones;
- Control of atmosphere to bring air purity where manufacture is carried on.

It is difficult to say whether all the homoeopathic manufacturers in India can be called upon to invest the required amount at one time. At the initiation of the Central Government, time can be given to the manufacturers for equipping themselves with necessary facilities to establish GMP in their respective factories. However, while allowing time for universal adoption of GMP standards, the Government can consider introducing measures to recognise manufacturers who observe such standards. A mark like AGMARK or ISP or ISO 9000 can be introduced and awarded to companies which fulfil GMP requirements. This mark, applied to products of qualifying companies, will enable consumers. institutional buyers, and homoeopaths to distinguish between products conforming with standards of excellence and others. I have tried to explain the underlying ethos of GMP and submitted why it so necessary to apply credible GMP guidelines to Homoeopathy.

Homoeopathy has a great future globally. India, with all our biodiversity and traditional knowledge, is eminently placed to play a major role in its growth. GMP will be the catalyst that will change the potential into reality.