STANDARDISATION OF HOMŒOPATHIC DRUGS WITH REFERENCE TO DRUGS ACT*

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HON'BLE PRESIDENT, LADIES AND GENTLEMEN,

I thank the organisers of this function in connection with the National Pharmacy Week, and I deem it a privilege to address this gathering of experts of different systems of medicine on the standardisation of Homœopathic Drugs with reference to the existing Drugs Act of our country.

The different systems of Medicine, e.g. Ayurveda, Yunani, Modern Scientific medicine and Homœopathy, all have come to stay in our country. It is in the fitness of things that the Government, people and the scientists should make an attempt to assess the values of each of them; and it is the bounden duty of our Government to render all possible encouragements to each of them and to provide ways and means of their development on right lines for the cause of the suffering humanity. Anything which has been discovered by human ingenuity for alleviating the ills that human flesh is heir to, should be reviewed without prejudice, without dogmatism and with a scientific mental attitide. "Allopathy, Homœopathy, Naturopathy, Osteopathy, Kaviraji, Hakimi", wrote Sri Aurobindo, have all caught hold of nature and subjected her to certain processes; each has its successes and failures." He continued "Let each do its work in its own way. I do not see any need for fights and recriminations."

Now that the different States of India have come to recognise Homœopathy through their respective State Legislative enactments and the Central Government of India, though not as yet introducing any Homœopathic Medicine Act on an All India basis, have lately constituted a Homœopathic Pharmacopœia Committee for the compilation of an official Homœopathic Pharmacopœia, it is expedient to regulate the import, manufac-

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ture distribution and sale of Homœopathic drugs and other cognate matters in our country; and the attention of the Central Government of India has been directed to incorporate all these relevant points regarding Homœopathic Medicines in the existing Drugs Act and the Drugs Rules. While nobody denies the importance and urgency of this matter I beg to place before you some of our comments and suggestions regarding the provisions of Chapters III and IV of the Drugs Act and the Rules.

I like to make some general remarks before coming to details, which are as follows:—

1. Homœopathic Pharmacy is much more simple, uncomplicated and clear-cut. It involves much less equipment and requires personnel whose qualifications need not be, at least, for the present, as high as those needed for carrying out Pharmaceutical works in connection with modern medicine. Homœopathic Pharmaceutical principles differ, to a great extent from those of modern medicine in some respects, viz. potency preparations in which the material quantity of drugs is almost non-existent and no known chemico-physical or electric tests exist as yet for the determination and identification of a particular drug in a potentised solution and tituration. Manufacture and dispensing of Homœopathic medicines are consequently much simpler compared to those of modern medicine. It is a moot point whether potency preparations of Homœopathic medicines can be grouped under manufacture as it is implied in connection with modern medicine.

2. Standardisation of drugs, control of manufacture and sale of drugs are undeniably needed for the cause of public health safety. But it is a much debatable point whether all the rigidities of Drugs Standard Control, Drugs Act and Drugs Rules, as enforced in connection with modern medicine (many of which are poisonous drugs) should be applied to the Homœopathic Medicinal Industry.

3. The smallness of capital involved in this industry, the total volume of work in the whole of India do not obviously call for so much rigidities and formalities which might lead to high cost of productions of Homœo. medicines, difficulty in supplying the required personnel, financial incapacity of many Homœo-

pathic industrialists and to many unnecessary complications of the overall working of this branch of industry. To facilitate its growth and development on proper lines much relaxation in the rigidity of the Rules, to be framed, should be observed in the beginning; and as the whole thing gets organised more and more, gradual tightening of the conditions, restrictions and obligations might be effected. The progress of Homœopathy will not be hampered thereby.

4. So it is suggested that the whole matter of Homœopathic Drugs Standard Control, should not be incorporated in the present Drugs Act and Drugs Rules but a separate legislative enactment for Homœopathic Drugs Act and Drugs Rules is preferred with suitable amendments peculiar to the Homœopathic orientation regarding drugs, their preparation and use in the practice of the Homœopathic system of medicine. One leading feature of this Act should be that all control measures should only be applied to manufacture of original mother tinctures and not to potency preparations which are not physical quantities but rather paraphysical qualities because they are some kind of energy not yet explained by modern chemico-physical sciences.

Coming to details, I like to touch upon the following items:—

1. Re: Standard American Homœopathic Pharmacopœia.

   The existing American Homœopathic Pharmacopœia need not be regarded as the only authoritative Homœopathic Pharmacopœia. The reasons being

   (a) It is not complete, does not include many important Homœo. remedies, not to speak of important Indian Drugs which are gaining increasing popularity for their therapeutic efficacy.

   (b) A Homœopathic Pharmacopœia Committee has been appointed by the Government of India for preparing the Indian Homœopathic Pharmacopœia and as such there should be no undue haste on the part of the Government to accept the American Homœopathic Pharmacopœia for a Standard one.

2. Re: Labelling on phials containing Homœopathic medicines:

Ordinarily single Homœo. medicines are supplied and in such case the question of mentioning their formula or ingredients cannot arise as their very names are sufficiently indicative to express what they are.

3. Re: Definition of "Homœopathic Medicine":

Definition of "Homœo. Medicine" must be comprehensive and clear-cut. There have not been complete or partial Homœopathic proving of many important drugs but they are used with success on the basis of their 'Clinical provings'.

The following definition is suggested:

Homœopathic medicines include any substance which is recorded in the standard books on Homœopathic Materia Medica by Hahnemann down to the present authorities, with symptoms gathered from proving on healthy human being; symptoms, not found in the provings but observed to have been actually cured (and verified by sufficient number of observations) by the substance during its administration on a sick person and symptoms observed as toxicological effects on human beings or animals either accidently or by controlled experiment; and which after being prepared according to the principles and technique peculiar to Homœopathic Pharmacy are administered to sick men in sub-physiological doses according to the Law of Similars and those substances include some used for external applications as sanctioned by the standard Homœopathic Pharmacopœias of foreign countries and our proposed Indian Homœopathic Pharmacopœia.

4. Re: The term "New Homœopathic Medicine":

It should be defined as a Homœopathic medicine which is not specified in the Indian Homœopathic Pharmacopœia, other foreign Homœopathic Pharmacopœias of U.K., U.S.A., or Germany or which is not specified in authoritative Homœopathic literature including Standard Homœopathic journals as efficacious under the conditions recommended.

5. Re: Manufacture of New Homœopathic Medicine.

Provisions in the Rules should be made to permit a manufacturer to produce a new Homœopathic Drug for other than commercial purposes, say, for instance, for experimental or proving purposes.

6. Re: The term "Manufacture".

It has been very widely defined in the Drugs Act. As it is, it is very difficult, so far as Homœopathy is concerned to determine where compounding or dispensing starts.

Will it be considered a manufacture or dispensing if a potency is prepared from its immediate back potency and (a) one drachm phial of it is sold or (b) more than 1 dr. phial or bigger than 1 dr. phial is sold to a single or different customers?

So a proper definition for the term 'manufacture' is necessary.

7. Re: Factory Premises Rule:

These rules should not be rigidly applied to Homœopathic Manufacturing concerns because of the small volume of work and smallness of capital employed in the Homœopathic Industry and of acute scarcity of accommodation now prevailing in almost all big cities, e.g. Calcutta, etc.

8. Re: Testing of raw materials and medicines:

Lack of properly trained personnel will stand in the way of testing, and manufacturing of Homœo. medicines will be held up or considerably hampered if testing is required to be done at other places. Therefore, provision for very gradual implementation of this clause should be made.

9. Re: Testing of Mother-Tinctures:

Although tests of active ingredients and solid matter may be made, they should not be made the only criterion for passing tinctures. As neutral glass phials are rarely available, specially of bigger sizes the clause regarding neutral glass phial should be deleted.

10. Re: Labelling of Homœopathic Medicine Phials:

It is impracticable to think of labelling Homœo-

pathic Medicine phials on the lines of modern medicine. 34 ml or even less quantity of potentised medicines are prepared at a time from which a maximum number of six 5 ml phials (present 1 drachm size of phial) can be dispensed. Therefore it is absurd to suggest putting of batch numbers everytime a potency is prepared. The same argument holds good in respect of putting date of manufacture on the label. Even the quantity of mother-tincture of a medicine that is ordinarily prepared is not sufficient enough to justify putting of batch no. and date on each phial. If this is to be enforced, at all, labels may be given on phials bigger than 125 ml size phials of mother-tinctures.

As almost all Homœopathic medicines contain alcohol a huge amount of labour will be required to mark on label of each medicine phial its alcoholic content even if phials of bigger size than 25 ml are required to be marked.

It is suggested that only in phials bigger than 125 ml there should be marking of alcoholic content.

11. Re: Inclusion of a list of Homœopathic medicines in Forms 24(C), 25(C) and 26(C) in connection with schedule 9:

In all these forms a list of Homœopathic medicines are required to be given. As unlike a manufacturer of modern medicine, a Homœopathic manufacturer has to handle such a larger number of medicine, enclosing of this list with the forms will be an impossible task. Therefore, a simple mention of Homœopathic medicines should be sufficient for the purpose of filling in the required Forms.

12. So many of the clauses of Chapters III and IV are inappropriate with regard to Homœopathic Medicines, that they may be amended *mutatis mutandis*.

These are the most salient points I can think of at present. We hope the Government of India will pay due regard to our suggestions while framing the rules with regard to Homœopathic medicines.