HOMOEOPATHIC POTENTIZATION

PROBLEMS OF QUALITY CONTROL

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The implementation of the Medicines Act 1968 and 1971 has drastically changed the pattern of the manufacture of homoeopathic medicines in the United Kingdom. As a result many thousands of pounds have been invested and a re-organization of manufacture has become necessary at Nelsons and Weleda over the last two years. Only these two companies remain as manufacturers of homoeopathic medicines in this country, and other companies have either closed, or reduced their activities to those of dispensing chemists.

It is not generally recognized that it is no longer feasible, or even legal—the maximum penalty being imprisonment—for anyone to manufacture allopathic or homoeopathic medicines unless they hold a manufacturing licence granted by the Department of Health and Social Security. In this context it is important to realize that the definition of manufacture, agreed with the Department of Health, embraces all processing steps up to and including the preparation of homoeopathic potencies. The multitude of legislative problems arising from the Act, involving, inter alia, product licences and pro-product licences of right, labelling regulations, advertising regulations and packaging regulations, apart from the requirements for the manufacturing licence, have placed a considerable burden on the manufacturers in terms of additional running costs, staff and capital investment. A manufacturing licence is granted when manufacture is carried out in premises which conform with stringent standards in relation to buildings, equipment and facilities, staffing and manufacturing and quality control procedures.

Leaving aside the problem of the considerable capital investment required, the increased overheads and the time-consuming paperwork in grappling with the legislative requirements, I would like to consider the regulations concerning quality control which are one of the positive benefits of this legislation. As a result of the detailed procedures laid down, there is no doubt that there has been a considerable improvement in quality standards generally in recent years, both in terms of purity and reproduceability. With few exceptions, the procedures laid down are good common sense. From the point of view of the homoeopathic physician, who relies on the efficacy of the medicines he prescribes, this benefit is therefore of fundamental importance. In spite of this, there are still a few people who regard the use of new scientific techniques and modern laboratory procedures with some suspicion. I must emphasize therefore, that modern techniques and systems of quality control do not invalidate the original Hahnemannian concept nor replace the classical procedures. Indeed, they are enhanced. I believe that had modern advances

in scientific and medical knowledge been available to Hahnemann, he, in his wisdom, would have certainly taken advantage of them. Hahnemann, of all doctors, could never be accused of being reactionary!

I would now like to outline the essential features of a comprehensive quality control system associated with the preparation of homoeopathic medicines. Before doing so however, I wish to emphasize that ultimately the attainment of a high quality standard is only possible if one can rely on the integrity, the involvement, the training and experience and the commitment of *all concerned. This is essentially a team activity in the true spirit of providing* a service to Homoeopathy, and the objective must always be to guarantee the purity, reliability and reproductability of the medicines supplied to the doctor.

An essential prerequisite for quality assurance is that personnel engaged in manufacture are adequately trained and experienced and their duties and responsibilities are clearly explained. *Training programmes usually involve* instruction both on-the-job, in the work situation, and off-the-job, in the classroom.

High standards of personal cleanliness must be maintained by all personnel and hand-washing facilities made available and used regularly. Protective clothing, including clean overalls and hats, must be worn at all times in manufacturing areas, not only by manufacturing personnel, but also by visitors entering manufacturing areas. Separate changing rooms are provided for this purpose. Stringent housekeeping methods must be employed and floors regularly washed and all surfaces where dust and dirt may collect wiped regularly. Utensils are washed thoroughly each time after use. Naturally, smoking, drinking and eating are not permitted in manufacturing areas under any circumstances.

It is a fundamental precaution that the person responsible for quality control must be a different person from the Production Manager and have the authority, independent of any other person, to carry out his responsibility impartially.

The first stage in any quality control system is the transfer of each delivery of incoming raw materials to a Quarantine Store. Each delivery or batch is allocated a reference number which can identify the material through each stage of manufacture, and a sample is taken for testing to ensure that it complies with Raw Material Specification in every respect. For example, botanical identification of plant raw material is carried out and, having *established their identity, they are examined for contaminations, such as* other plant species, dirt, mould or insects.

Specimens may be dried and pressed for retention, or photographed and, in certain circumstances, subjected to microstructure analysis from which microphotographs are taken. Release of all raw materials from the Quarantine Store for use is made only on the authority of the person responsible for quality control and if they are labelled as fit for use. Rejected materials are

promptly destroyed. Labels for the finished packed product are also subject to quality control inspection, to ensure their accuracy and check for misprints, before they are released to the production area.

At commencement of each manufacturing step, all equipment is inspected to ensure it is clean and free from contamination from any other raw materials or products. At each stage, all materials and equipment are carefully labelled to identify the material being processed and each discrete quantity of raw material or product is labelled with a batch number. Written manufacturing procedures are closely followed in each manufacturing step and batch records are completed, indicating times, temperatures, weights etc. Thus, the history of each batch, including the utilization of raw materials and even packing materials, may be checked.

At any time during manufacture and packaging of homoeopathic medicines, quality control personnel are required to make spot checks and take samples for laboratory analysis, thus monitoring every operation. Particular care is taken in the preparation of mother tinctures and potencies, to ensure absolute purity and reproduceability.

On completion of manufacture, representative samples of the finished product are taken according to prescribed procedures and labelled with the batch number and identity. Analytical tests are carried out in the laboratory to ensure that the product meets the Finished Product Specification and then —and only then—is the product finally released from quarantine to the store to await despatch. Samples of each batch of finished product are always retained in the laboratory. Storage conditions are carefully controlled to ensure the produets do not deteriorate before being passed to the doctor. Finally, all manufacturing records are checked and filed and all equipment utilized in the manufacture is cleaned in accordance with Cleaning Schedules, which lay down cleaning and inspection operations for each individual item of equipment.

General precautions to ensure quality which apply to all manufacturing operations include the segregation of processing areas to avoid possible cross-contamination, the use of laminar air flow equipment or air conditioning, and all operations carried out in such a way that the risk of contamination is minimized. A recent innovation is microbiological testing by swab or settle plate method to monitor environmental contamination of all manufacturing areas.

Turning our attention to the problems of quality control associated with homoeopathic potencies. This is an area which presents the greatest challenge to the quality analyst. We do not know or understand, yet alone measure, the intrinsic forces or vibrations which may play a part in the healing process of homoeopathic potencies. Furthermore, the extremely high dilution of homocopathie potencies make it almost impossible to apply analytical tests by conventional methods in the laboratory. Even a relatively low potency such as 6x, with concentrations of individual 'active ingredients' less than

one part per million, is outside the accuracy of many modern instruments. For this reason, only mother tinctures are subjected to a more comprehensive analysis, both qualitative and quantitative. Additionally we have the problem of the chemical complexity of the natural extract contained in the original mother tincture. These may be inorganic or organic, with complex mixtures including minerals, amino-acids, proteins, steroids, vitamins, organo-metallic compounds, alkaloids, etc.

This brings me to a most important point. The conventional allopathic approach to quality control in manufacture is to place great reliance on the assay of the final product, which usually incorporates one or two readily identifiable "active ingredients", all of them at relatively high levels of concentration. Because of the complexity and the high dilution of homoeopathic remedies, as I have described, this approach is not possible and therefore the Department of Health, quite rightly in my view, consider that 'in-process' quality control, embracing every step of the preparation, from raw material to finished products, is critical in ensuring the purity and safety of homoeopathic medicines. Thus a system of quality control is even more vital in their manufacture than with their allopathic counterparts.

We are pleased to report that we at Nelsons have recently developed a device for detecting electronically the presence of medicament in all homoeopathic pharmaceutical forms—tablets, granules, pilules, ointments, etc. This represents a major step forward in quality control. The test is very sensitive, even on materials which have been specially dried after medication, and it enables us therefore to monitor any homoeopathic medicine from any source in the future.

Finally I would like to comment briefly on the present methods employed and the progress we are making to identify and examine the constitution of mother tinctures which are used in the preparation of our potencies.

Physical properties: Mother tinctures and liquid potencies may be tested routinely for their physical properties, including specific gravity, refraetive index, colour and smell.

General tests: These may include dry residue (total solids), pH, water content by Karl Fisher technique and percentage alcohol content.

Analysis of chemical elements: These assays are carried out by conventional chemical methods and can provide a means of identification and a guide to the purity of mother tinctures, and even for low potencies. An example analysis is given below, which illustrates the wide variation between different mother tinctures:

	Crataegus ϕ	Nux vom. ϕ
Iron, parts per million	1.9	0.3
Calcium, parts per million	1500	1.9
Sodium, parts per million	16.0	6.8
Sulphur, per cent	0.003	0.005
Nitrogen, per cent	0.005	0.005

Other trace elements present in low concentration include zinc, potassium, copper, cobalt, selenium, magnesium and manganese. Differences in assay occur between mother tinctures prepared from plants grown in different locations. For example, a plant grown in limestone soil would be expected to have a higher calcium content than the same species grown in sandy soil.

Thin layer chromatography: This technique is now widely used and shows characteristic bands on a layer of silica gel of 25-250 μm thickness, each band representing a specific chemical constituent of the mother tincture. These bands constitute a 'thumb print' for each mother tincture which can be used as a means of identification not only for the mother tincture itself, but different batches of the same mother tincture. Various solvent systems have been used, such as butanol/acetic acid or methanol/chloroform over development distances of about 10 cm. A comparison of British, French and German mother tinctures showed considerable variation of composition which arises primarily from the variation in the composition of the soil in which the original plant specimen was grown.

Microcrystallography: This technique, developed in our own research laboratories, provides a spectacular illustration of the variety and complexity of homoeopathic medicines. Tests are performed by making a balanced mixture of chromium and nickel salt solutions with the mother tincture of the plant. The mixture is then crystallized under controlled conditions of humidity and temperature and the resultant crystal pattern photographed under the microscope using a special filter system. The crystallization pattern is characteristic of the particular mother tincture and provides a means of identification. Unfortunately, this technique is not feasible with liquid potencies.

It is with some humility that we must record that, of over a half a million different plant species on this earth, only 5 per cent or 10 per cent have been examined for their homoeopathic potential. Further, it is clear that our understanding of what constitutes a homoeopathic remedy, even chemically, *may be described as groping in the early morning mists of one day of homoeopathic progress*. I hope that our successors will view our present position in this way as we may then know that Homoeopathy would have reached its true potential.

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