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The Standardisation of Drugs and Chemicals

Medicine is closely meshed with the gears of our social and economic organization, and the problem of public health is bound up as much with the skill and efficiency of medical care, as with the purity and strength of the drugs employed by the profession in alleviating human suffering. In 1930 the Government of India appointed the Drugs Enquiry Committee under the chairmanship of Sir Ram Nath Chopra to investigate the question of adulterated and low standard drugs freely offered for sale, and to submit recommendations for combating the menace to public health, and for controlling the ethical drug trade and the scientific medical practice in India. After a comprehensive examination of the whole problem in all its various aspects, the Committee emphasised the need for the enactment of a measure by the Central Legislature for the control of the importation, manufacture, sale and distribution of adulterated and substandard drugs, and secondly for the establishment of a machinery for the systematic collection and testing of drugs to secure conformity to proper standards of purity and strength. On the basis of these recommendations, The Indian Drugs Act was passed in 1940, and the nucleus of a Central Laboratory (which later was developed into

Bio-chemical Standardisation Laboratory) was founded in 1937 as an adjunct to the All-India Institute of Hygiene and Public Health in Calcutta. The Laboratory which has grown from small beginnings, is now fairly satisfactorily equipped for research work of a high character in the science and art of preparing drugs, and is provided with a Bio-assay Section for acute and many chronic experiments in connection with hormones and vitamins.

Perhaps the most interesting section of the Laboratory is the Drug Museum, which is to function as a reference centre, and where various types of pharmaceuticals and biological products which are commonly found adulterated, under-strength or misbranded in the open market, either as a result of wilful adulteration or subterfuge or as storage deterioration, will be properly displayed.

... In the initial stages, the work of the Laboratory was mainly confined to routine analytical work of certain definite drugs of comparatively greater importance, and attention was accordingly concentrated on surveying the quality of Tincture Digitalis, Tincture Strophanthus, Tincture Scilla, Posterior Pituitary Extract, and Adrenaline Hydrochloride Solution, including among these a few samples of insulin, organic antimony, and arsenic compounds and sulphonamide preparations. This survey has shown that out of a total of 1,044 samples of pharmacopoeial preparations, nearly 480 or 46 per cent do not satisfy the standards laid down. "There cannot therefore be any doubt about the seriousness of the situation regarding the drug adulteration existing in this country". Analysis of other pharmacopoeial drugs, those mentioned in the British Pharmaceutical Codex 1934, patent, proprietary and miscellaneous remedies and Hospital mixtures and solutions revealed that a very large percentage fell below the

specifications claimed by the manufacturers and dispensing agents. Though the results of investigation may bring to light the poor quality of medicines ordinarily supplied to the people, yet they prove that the constitution of the patients is of the appropriate standard. . . .

The excellent and far-reaching results obtained by the Laboratory must find a wider application than merely an appreciation of the quality of drugs, for the imposing array of facts and enlightening figures must have a deeper significance in relation to a better organization of medical care. The needs of a vast population of a country like India cannot be estimated by doctors alone; the problem is to be investigated by social scientists, economists and government administrators. What emerges as a result of scientific comparative study of all the possibilities of improvement should form the basis of a comprehensive policy of reorganization of public health administration. We have hardly an adequate conception of what constitutes a proper medical care and insurance of public health, for the problem transcends the scope of medical relief. We have to deal not only with the medical and scientific problems relating to drugs, but also, with the social and economic problems as well, and unless these two aspects of the insides of family situations and of homes are thoroughly understood, the efforts of laboratory standardisation of drugs alone can afford but a partial alleviation.

... Of outstanding interest to us in the whole report is the fact that medical scientists will find in the results of investigations conducted in the Laboratory, new fields for organizing medical care and for planning for the health of the population and for the formulation of proposals for advancing medical science, raising standards of medical practice and for improving medical education.