CURRENT SCIENCE

Vol. X] AUGUST 1941 [No. 8

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, understrength or mis-branded in the open market, either as a result of wilful adulteration or subterfuge or as storage deterioration, will be properly displayed.

The triennial report of the Laboratory just issued is an impressive document, recording achievements during the period of 1937–40 whose significance will be of the highest importance, not only as a measure of fulfilment of the chief functions outlined by the Central Drugs Laboratory, but also as a means for a better organisation of public health work. 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 Hydro-chloride 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 pharmacopœial 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 pharmacopœial 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. Perhaps a more alarming picture would have been presented, if proper arrangements had been made for the checking of imports, policing of manufacturing houses and frequently inspecting the retail dealers' stores. With the enforcement of the Drugs Act, perhaps a more wide-spread and constant vigilance is now possible.

The Laboratory has a very comprehensive routine work, the functions including the assaying and testing of chemicals, drugs, biological products and organometallic compounds, standardisation of methods of analysis and tests with due regard to the climatic and other conditions prevailing in different parts of India, in addition to undertaking tests of commercial drugs for manufacturers and dealers, preparation and maintenance of stable standards of strength,

purity and quality of drugs. The Laboratory acts as a "National" distributing centre for International standards, aside from acting as an expert referee in respect of disputed analysis. Important as this work must be in guaranteeing the appropriate specifications of important remedies for general use, the Laboratory influence as a scientific centre will be exerted in the field of researches on pharmacological testing of drugs, in guiding and co-ordinating the work of the Provincial Government laboratories, and in serving as the training ground for "public analysts" in the methods of chemical, biochemical and biological assay. With the object of warning non-ethical and fraudulent manufacturers and distributors in India, and also with the object of creating a consciousness amongst the consuming public of the importance of the problem of drug adulteration from the public health point of view, the Laboratory has carried out propaganda by the publication of informative articles and through press circulars.

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.

It is impossible to read the Report profitably unless it is borne in mind that the aims and purposes of the Laboratory traverse beyond the strictly scientific or professional angle, and we are convinced that the intent of the manifold investigations is to prove in order to improve human existence. We are poignantly aware that the human problem is of subtle composition, capable of being solved not by laboratory experiments only but by investigations guided by all the resources of science and statesmanship. 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.