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BY

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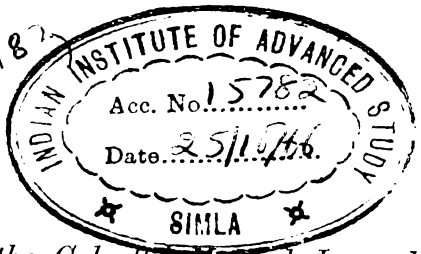

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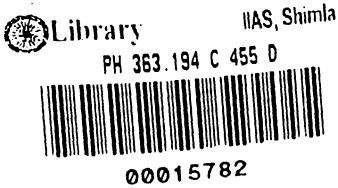

ADULTERATION AND SPURIOUS DRUGS IN INDIA*

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Introduction

That the market in India was being flooded by unscrupulous traders with drugs and chemicals of defective strength and impure quality and that potent remedies, such as sera and vaccines were being freely sold to the public without their quality being tested, was pointed out in the Council of State as early as 1927 by the Hon'ble Sir Haroon Jaffar. He characterised the practice as a great menace to the public health and called for the prompt institution of efficient 'safeguards' to ensure the quality and authenticity of medicinal preparations offered for sale to the public. The discussion that followed showed an appalling state of affairs and the Council recommended to the Government of India to urge all Provincial Governments to take such steps as may be necessary to control this state of affairs. In the Legislative Assembly Col. Sir Henry Gidney stressed the fact that India was *par excellence* the dumping ground for every variety of quack medicines and adulterated drugs manufactured in all parts of the world and that her markets were glutted with useless and deleterious drugs sold by unqualified chemists, who were themselves a public danger. He pleaded strongly for the immediate introduction of effective legislation to eradicate the existing evil.

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The commercial community were also alive to the fact that a large number of chemists and druggists stocked drugs of inferior quality for sale and that this had adversely affected the pharmaceutical industry in this country. Public opinion expressed itself in no uncertain terms and medical and scientific journals took up the question. The Indian Medical Gazette described India as "a land of quacks, quack traders and quack medicines." The leading newspapers in India vigorously championed the need for legislative interference to protect the masses from the perils of the situation.

Drugs Enquiry Committee

In response to this volume of opinion, the Government of India appointed a small *ad hoc* committee to explore and define the scope of the problem with reference to actualities and to make recommendation. As Chairman of this committee the author had the opportunity of coming intimately in contact with the problem as it existed all over India. The Committee started work in October 1930, toured all over India and received a large mass of varied and voluminous evidence, both written and oral. It heard a wide range of opinion on both the medical and the commercial side of the problem. All aspects of the question were carefully and systematically considered. The committee found that the situation as described in the Council of State and the Legislative Assembly was not in the least bit exaggerated ; in fact it was even worse and called for stringent measures to cope with it.

It is nearly four years since the Committee completed its labours and made its report. On account of financial stringency it has not been possible for any action to be taken and the position has not been improved. It would in fact appear from various reports that have been published in the press from time to time in different provinces that things have gone from bad to worse. In Bombay spurious drugs with counterfeit labels having the names of well known firms have been seized recently (February 1935), and the committee of the Bombay Chemists and Druggists Association has passed and forwarded to the Government a resolution of

apprehension and great alarm on the ever-increasing menace of adulteration of drugs prevalent in the country and of the frauds committed on the general public by unscrupulous dealers and fakers, to the detriment of the health of the public. A similar resolution reached the Government of India from an important body in the United Provinces last August and there is no doubt that the situation all over the country is the same. The author can say from personal knowledge of Calcutta, which is one of the biggest drug trading and manufacturing centres in India, that the state of affairs is chaotic in the extreme and manufacturers of standard products are suffering heavy losses. We will now discuss briefly how different classes of drugs are affected.

The quality of drugs and chemicals on the market in India : Pharmacopœial Preparations

Firstly, we will explain the extent to which the drugs and chemicals of the British Pharmacopœia which are of impure quality or of defective strength are imported, manufactured or sold in India. This is the central problem, as this group of drugs is the largest in use. There is unfortunately no room for doubt that in regard to adulteration, deterioration or tampering with the quality and strength of drugs, very little distinction could be made between imported and locally manufactured medicinal preparations.

It is well known that firms abroad manufacture drugs specially for the Indian market and in the absence of control on the quality of drugs manufactured for export, these countries are able to undersell the local manufacturer of drugs. The dumping of inferior quality of drugs has its repercussion on the quality of drugs manufactured in India, in that the quality is deteriorated to keep pace with the competitive rates of the dumped goods. A class of manufacturer has thus arisen who make and sell inferior and sometimes absolutely inactive products. Having regard to the seriousness and far-reaching character of the problem, the Drugs Enquiry Committee collected a large number of samples at random from different provinces and we subjected them to a careful analysis in our own laboratory. It was definitely proved that not only

was adulteration common, but many firms sold packages which were considerably under-strength and under-weight. A perusal of the report of the committee will show what a large number of preparations are involved. The medicinal preparations were found considerably below strength and instances were met with where "quinine was entirely omitted from quinine tablets".

This state of affairs is in no way altered since and there is no doubt whatever that the drugs on the Indian market at the present time are not above reproach and many of them are of impure quality and defective strength. We can say from personal knowledge that the traffic in such drugs at the present time is extensive and indiscriminate and the statements which have recently appeared in the press are in no way undeserved and exaggerated.

Non-Pharmacopœial Preparations

The *second* large groups of drugs are those which are not officially recognised by the British Pharmacopœia but are known and approved medicines and are largely used. The extent to which such drugs of impure quality and insufficient strength are indiscriminately manufactured, sold or imported is the same as that of the Pharmacopœial drugs. The groups of biological products include sera, vaccines, preparations from animal glands, hormones, etc., besides these there are complicated organo-metallic compounds containing arsenic, antimony etc. Those imported into the country are frequently made by reliable firms of manufacturers having an established reputation. The climatic conditions and defective storage, however, may produce rapid deterioration in their potency and it is well known that many of the retail sellers have not proper arrangements for storage of these products. Some of the importers do not hesitate to descend to the vile practice of getting hold of time-expired biological products from the European markets and importing them into India and selling them to the dealers at a very cheap rate.

As regards those manufactured in this country, very few of the firms in India have the personnel and equipment

to produce these products and therefore many of the preparations are not up to standard. Unfortunately complicated compounds of arsenic and antimony can be manufactured in India by anyone who may choose to do so and these potent compounds are being actually put on the market without their toxicity and strength being properly tested. Their standardisation is at present left entirely to private enterprise and to manufacturers and each maker is free to adopt his own conception of adequate standardisation ; there is no check whatever by the State.

In other countries the toxicity of each batch of such complicated and potent preparations has to be carefully tested before they are allowed to be sold to the public. No license is granted to any firm until the licensing authority is satisfied that the personnel and equipment of the firm is qualitatively and quantitatively efficient for the purposes for which license is sought. In addition to this licensing system, samples of finished products are tested by the laboratories under State control. While in other countries careful watch is kept over these potent compounds the Indian public is entirely unprotected. The position indeed is discreditable to the country and is a source of great danger to the public. We have recently tested some of these compounds whose toxicity is high and yet they are being sold to the public, one shudders to think with what consequences.

Proprietary Preparations

The *third* group of drugs we are concerned with are the patent and proprietary medicines. The Indian market is inundated with proprietary and secret medicines both imported and of Indian origin, and their sale is increasing by leaps and bounds. The public in India consume them voraciously on account of the ingenious propaganda, and clever and alluring advertisement of their supposed virtues. The credulity of the masses, especially when 'certain cures' are assured in utterly hopeless cases, can well be imagined. Perusal of advertisements of 'cures' produces a great effect on the patients who have tried treatment by medical men without success. The promise of cure, the force of argument

advanced to guarantee it and the certificates of persons said to have been cured (who often do not exist at all) which are all set out in the advertisements make a deep impression. There is no doubt that while there are useful preparations among these, there are also positively injurious and fraudulant combinations and on account of the lack of any State control in this country, their number is quite large.

Results of Drug Adulteration

The substitution of genuine medicinal products by rubbish has now reached a very serious stage and its results can be easily imagined. In the case of *Pharmacopœial drugs* the patients to whom these drugs are prescribed will not naturally benefit by them. In diseases such as pneumonia, diphtheria, etc., it may make all the difference to the life of the patient whether he is getting a drug of proper strength or an adulterated or useless preparation. In case of complicated *organo-metallic compounds* if they are not properly prepared and tested and in a state of absolute purity, their use will be positively dangerous and fatalities may occur. In the case of *biological products*, incalculable harm may follow the use of products which are improperly prepared or stored. The injection of faked insulin in cases of diabetic coma may lead to the death of the patient. The Medical Research Council in England have described the absence of control over these products to be "a source of grave danger to the country."

The misery, breakdown in health and mortality that might follow the use of some of the *patent and proprietary and secret medicines* cannot possibly be overestimated. Much harm may result from the use of such medicines in negative as well as positive ways. A patent medicine might be injurious and cause direct harm as some of the constituents may be positively dangerous in absence of control. Some medicines might have the effect of masking early symptoms of serious and grave diseases and assuaging them for a short period, result in delaying scientific diagnosis and treatment. Much valuable time may thus be wasted and investigation delayed until it is too late to do anything. It is for this reason that rigid control is exercised in many

countries over extravagant claims made in advertisements and the law prohibits statements which are untrue, deceptive or misleading.

The Remedy

How can the present unsatisfactory position be remedied? The Drugs Enquiry Committee has gone very carefully into the whole question and worked out a scheme by which control can be exercised on the medical preparations. This scheme has been generally accepted as being sound and effective. The essential parts of the scheme are *firstly* legislation and *secondly* machinery to collect and test drugs.

Effective Legislations

So far as the existing legislation is concerned, there is no enactment in the Indian legislature which aims directly at the prevention of adulteration or which ensures conformity to proper standards of purity and strength. Certain sections in the Indian Penal Code, the Indian Merchandise Marks Act (1889) and the Sea Customs Act contain some provisions bearing on it, but in actual practice they are difficult of application. The result is that mere adulteration of drugs is not, by itself, prohibited in British India by enactment. Nor is the sale of a drug of insufficient strength or improper standard punishable except on the basis of "misrepresentation" and 'fraud'. These expressions are vague and are of inconclusive import. The baneful results of adulteration or defective strength of drugs may be slow and gradual in making themselves evident. The non-existence of fixed standards or methods of analysis, the absence of any precise definition of adulteration, the want of skilled experts and of well-equipped laboratories, the difficulty of proof and the fact that intention or knowledge is the essence of these offences, as well as cheating, complicate the situation and render the provisions ineffective in actual practice.

The Calcutta Municipal Act of 1923 and Bengal Municipal Act of 1932 deal with food and drugs in a fairly comprehensive manner; the former defines the expressions "adulterated" and "misbranded" in relation to foods and

drugs, but unfortunately there is no machinery to work these. Most of the other provinces have some sort of legislation. For proper control of drugs, however, there should be central legislation for the country as a whole, because that is the only way in which effectiveness and uniformity of control throughout India can be brought about. This part of the scheme does not need any monetary expenses and could be proceeded with at once.

Laboratory for Testing and Standardisation

The machinery to test medicinal preparations consists of a well-equipped central laboratory with competent staff of experts in various branches, as well as provincial laboratories working under the guidance of the central laboratory. The provision for control includes the appointment of inspectors, who will be appointed by local governments to pick up specimens and send them to the provincial laboratories for testing. It will thus be seen that in any scheme of control the Central Government as well as the Provincial Governments must take part. This portion of the scheme is bound to cost money in the beginning though later on a good deal of revenue will be obtained. On account of financial stringency funds have not been forthcoming, with the result that we are now in the same position as regards the control of drugs as we ever were.

Training and Control of Pharmacists

In all fairness to the Central and Provincial Governments it may be said that the problem in India is not so simple as it looks. The profession of pharmacy is still unorganised in India and the question of the purity of drugs and the profession of pharmacy are interdependent. The important part which the pharmacists play in relation to drugs needs no special emphasis. They are the custodians of drugs. They prepare, compound and sell them, and on their efficiency depends the purity of the drugs dealt with by them.

To ensure efficiency in discharge of duties and quality, it is essential that the pharmacists should be properly trained and brought under control. An untrained person cannot appre-

ciate the value of scrupulous accuracy and the importance of purity and strength of medicinal preparations. In most parts of India at present anybody can compound and sell medicines. My Committee worked out a scheme for organisation of the profession and for properly training and registration of those who practice it as a part of drug control. This is the only thing which will make them realise their responsibility and thus help towards the disappearance of adulterated and spurious drugs.

Indigenous System of Medicine

Another problem which complicates matters in this country is the practice of the Indian systems of medicine and the drugs used by them. A very large proportion of the population, particularly in the villages and small towns resort to the indigenous systems of treatment and there is no doubt that many of the crude drugs as well as the compounded medicines offered for sale to the public are adulterated and of poor quality. Many of the practitioners in these systems use potent and toxic substances over which control is absolutely essential. It has been urged that if any legislation is undertaken for insuring the purity of drugs, it should not be confined to drugs used by a small section of the population, namely those resorting to the western system of treatment only and one may be disposed to argue that legislation which aims at disposing the drugs used by western system only will be truncated and lack in completeness or perfection. In the absence of standards, however, these drugs cannot be treated on the same lines as drugs and chemicals recognised by the British Pharmacopœia and other western preparations. The only possible way is to keep the drugs and preparations of the indigenous systems separate at present; yet another difficulty is the existence of foreign territories and Indian States in close proximity to the provinces.

Co-ordinated State Control

Such is the problem of adulteration of drugs and its control with which we are faced in this country. The problem is undoubtedly a difficult one, but a remedy must be

found to rectify the present state of affairs. Although public health is essentially a provincial subject, food and drugs have not attracted the attention of local legislators to the extent they deserve. Drugs have fared worse than foods in this respect. We have already emphasized that no system of control in which the Provincial Governments do not take their due share along with the Central Government will be workable. Both must do their bit.

An editorial in the Statesman recently under the title of "Keeping a nation fit" reviewed the report of the British Ministry of Health of which the control of drugs forms a very important part. It pointed out that expenditure on public health is a long-term investment and that purity of food and drugs is the first line of attack in the unceasing war against disease and epidemics. Those who have the control of the purse in this country should follow the lead given by Britain, who has invested large sums of money on public health matters and is already receiving the dividend on the long-term investment. The Indian statesmen will, we hope, view this problem with the same breadth of vision as statesmen in other civilised countries.