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Standardisation of Vaccines, Toxins, and Antitoxins.

WE referred last week to the special measures proposed by Sir Mackenzie Chalmers's Committee for the control of the quality and authenticity of vaccines, toxins, antitoxins, salvarsan, and certain other drugs. What is there in the special circumstances of our time to justify a closer superintendence of the many new therapeutic substances now in common medical use? It might well have been supposed that in the vast technical developments of the last half century "big business" had, through the sheer excellence of its scientific methods, reached a plane where further public control was superfluous. Over a large area of the drug field this is true. If we look back for half a century we can trace, since the medical Acts, a steady growth in the technical standardisation of all the drugs used in medicine. The British Pharmacopœia itself came into existence because experimental pharmacology showed the need for precision of dosage and the consequent standardisation of drugs. The demand made by scientific medicine evoked the best powers of scientific chemistry. To-day there are few fields of applied science that can show greater precision of practice than the drugs now used as therapeutic substances. Standardisation, therefore, and control in one degree or another are accepted methods of securing the consumer not merely against fraud, but also against inertness and inefficiency in chemical medicines.

But within the half century there have arisen other products not capable of easy standardisation. It is only some thirty years since Koch produced his first "tuberculin." To those who remember the wild rush to Berlin to secure the magic poison and to inject it without afterthought, the memory is full of horror. The damage done by the indiscriminate use of tuberculin alone would justify severe restrictions on the use of all such toxins, and the antitoxins had also to pass their trial. It is only twenty-five years since von Behring's diphtheria antitoxin was given to the world. Immediately, in this and other countries, von Behring's processes of production were imitated, sometimes without his exactness of technique, and the result was here and there a serious disaster. For even the large firms had not evolved the superb machinery they now command, and every person that used the new antitoxin did so with uncertainty and misgiving. Steadily, as methods improved, standards of potency and purity improved with them. Fortunately, diphtheria antitoxin from the beginning was capable of very exact standardisation by controllable units. It was the model for all later antitoxic serums. Of such serums many have since been produced, and some have succeeded as cures. But still more recently the treatment by vaccines has grown by leaps and bounds.

When Koch's tuberculin, which is really a dead-germ vaccine, appeared, many of the "elder statesmen" of medicine prophesied a period of specialised vaccines of endless variety. The period is now upon us. The refinements of technique are almost incredible. Smallpox vaccine was for a century the pioneer. To-day every common cold has its vaccine. This is because bacteriology has been active, methods have grown in scientific precision, and clinical medicine has come to understand the therapeutic value of biological products. But these products vary in potency, in purity, and in danger. In careless hands they may do immense harm; in skilled hands, immense good. But if widespread use and possible occasional danger are relevant grounds for control, the case for the control of these biological products is as strong as the case for the control of other potent and dangerous drugs.

The Committee's remit covered, however, other substances perhaps as dangerous. Salvarsan is a type of product that cannot be adequately tested by direct chemical means. Its toxicity is a primary

factor, and this cannot be tested except biologically. During the war, on account of difficulties with imported salvarsan and its analogues, special provision was made for testing and standardisation. The Medical Research Council undertook the necessary work, and the history of the uses of salvarsan and its substitutes is one of the most striking chapters in the records of the war. What the war started this Committee proposes to continue.

Standardisation, therefore, of biological products and of the more dangerous chemical toxic drugs is loudly called for. As early as 1909 the General Medical Council approached the Government with the suggestion for "the establishment of a public institution for the pharmacological standardisation of potent drugs and of serums." The Medical Research Council within the last few years has actually carried out a certain amount of standardisation. The recommendations of Sir Mackenzie Chalmers's Committee are really only giving effect to views accepted both by scientific experts and by scientific manufacturers. The primary recommendations are that such products as we have named should be subject to supervision and control; that the controlling authority should be the committee of the Privy Council which at present controls the Medical Research Council; that this committee should decide from time to time what substances are to be brought under control and prescribe the methods of standardisation and testing; that the controlling authority should have to assist it an advisory committee representative of the different sections of the kingdom, as well as of the Navy and Army, the General Medical Council, the Medical Research Council, and the Pharmaceutical Society; that there should be a central laboratory under the management of the Medical Research Council for the preparation and maintenance of standards and the testing of market products; that control should include the licensing of manufacturers, the inspection of plant, premises, and processes, and the testing of the finished products; that the primary responsibility for seeing that products conform to standard should lie with the manufacturers; that test samples should be taken from time to time, and also that manufacturers should be required on occasion and for a period to furnish samples of every batch of a substance made. It is also suggested that imported products of the same order should be admitted only by licence, and subjected to equal tests.

In these recommendations and in the argument justifying them we find nothing that should interfere illegitimately with the well-established methods of private enterprise. Indeed, the Committee, in its recommendations, has the support of the leading manufacturing firms, which, with certain slight qualifications, welcome appropriate inspection and standardisation. The draft Bill embodies the recommendations in a workable form. It may require modification in detail, but in principle it seems adequate. It combines a sufficiency of central control with the minimum of trade restriction.

British Dyestuffs Corporation.

THE situation in which the directorate of the British Dyestuffs Corporation finds itself is a remarkable one. At the registration of this company in May, 1919, as a result of amalgamating British Dyes, Ltd., of Huddersfield, with Messrs. Levinstein, Ltd., of Blackley, the appointment of Sir Joseph Turner as commercial managing director, and of Dr. Herbert Levinstein as technical managing director, was designed to maintain the interests of both groups, and to benefit the united enterprise by the special contribution of knowledge and experience which each of these gentlemen was expected to make. At the meeting of shareholders in Manchester on Friday last it was announced that Sir Joseph Turner and Dr. Levinstein, while retaining their seats on the board, have been superseded as managing directors by Sir Henry Birchenough, the chairman of the corporation, Sir William Alexander, and Mr. Vernon Clay.

It is no reflection on the new managing directors to express the opinion that the position thus disclosed must arouse grave misgiving amongst all those who recognise the foundation of a self-supporting synthetic dyemaking industry as a matter of the greatest national importance. Disregarding the woeful absence of harmony which appears to be indicated, the aspect of this rearrangement which causes anxiety to chemists is the fact that, at a time when all the scientific knowledge and commercial energy available in this country should be correlated in a concerted effort to establish an industry which, more than any other, depends for success upon the combination of these factors, two of the most experienced practitioners should be removed from very intimate association therewith.

The proper and perfectly natural request for an investigation put forward by the shareholders met with a cold response from the board, and the