MINISTRY OF HEALTH.

REPORT OF THE DEPARTMENTAL COMMITTEE ON THE CONTROL OF CERTAIN THERAPEUTIC SUBSTANCES, 1921 (CMD. 1156).

THE substances included in the terms of reference were classified into three groups: (*A*) Bodies described in the U.S. Regulations of 1919 as "biologic products," —*i.e.*, vaccines, sera, toxins, antitoxins, and analogous products. (*B*) Synthetic remedies, such as salvarsan and its analogues. (*C*) Substances corresponding more nearly with the popular definition of ordinary "drugs"—*e.g.*, preparations of digitalis, strophanthus, squill, ergot, cannabis indica, pituitary gland, etc.

An account is given of the present position as regards standardisation and control of substances which cannot be adequately tested by direct chemical means, together with an outline of the systems of control adopted in U.S.A. and Germany.

Evidence was given before the Committee by scientific authorities and representatives of commercial and manufacturing interests, and the following is a summary of the principal recommendations based upon this evidence:

(*a*) That therapeutic substances which cannot be tested adequately by chemical means should be subject to supervision and control.

(*b*) That the Controlling Authority should be the Committee of the Privy Council which was appointed by an Order in Council dated 11th March, 1920, under powers conferred by the Ministry of Health Act, 1919.

(*c*) That the Controlling Authority should be assisted by an Advisory Committee which might consist of members nominated by the Minister of Health, the Secretary for Scotland, the Chief Secretary for Ireland, the Naval and Military Authorities, the General Medical Council, the Medical Research Council, and the Pharmaceutical Society.

(*d*) That there should be a Central Laboratory under Government control, wherein standards would be prepared and maintained, research carried out in connection therewith, and tests made to ascertain that the products issued by manufacturers conform with the standards laid down. The Medical Research Council, who already possess the requisite organisation, should be responsible for this Central Laboratory.

(*e*) That the method of control should include the licensing of manufacturers, inspection of their plant, premises, and processes, and the testing of the finished products.

(*f*) That, with certain exceptions, testing by the Central Laboratory should be confined to samples taken from makers' stocks or bought in the open market, leaving to the manufacturers the primary responsibility for securing that the products conform with the prescribed standards and tests. That power should, however, be taken to require a manufacturer to submit for central testing, for a stated period, samples of every batch of a substance made.

(*g*) That power should be taken to inspect all premises where the substances are made and the several processes of their manufacture, but that in the case of salvarsan and its analogues (Group *B*) and of the galenical and other preparations which we have classified as Group *C*, inspection should ordinarily be confined to the records and methods of biological testing, and, when necessary, to the filling and sealing of the containers.

(*h*) That products made abroad should be subject to restrictions similar to those applying to products made in the United Kingdom, and that licences should be granted to approved manufacturers based upon a preliminary inspection of plant, premises and processes, and testing of samples. In addition, steps should be taken to ensure that each consignment attains the standards laid down for similar products of home manufacture.