"Noting, however, with apprehension, that certain Member States are prepared to place their facilities for quality control at the disposal of other countries, upon request to W.H.O. or direct to the Member States.

"1. Considers that the formulation of generally accepted principles for quality control of pharmaceutical preparations entering international commerce and their adoption by all Member States are desirable: and

"2. Requests the Director-General:

"(i) to proceed with the formulation of such principles.

"(ii) to continue to assist Member States in developing facilities for quality control of drugs they may have to import, or in securing access to facilities elsewhere; and

"(iii) to report to the Twentieth World Health Assembly."

Professor Geric (Yugoslavia) opened the discussion (quoted from page 2—A20/P&B/SR/8. and recalled "that the head of his delegation had referred, in the general discussion to quality control of pharmaceutical preparations as a question to which his delegation attached particular importance. The subject had been considered by the Health Assembly for many years. There was still inadequate control of preparations *exported* to the developing countries and on occasion *out-of-date preparations were exported.* It was apparent, accordingly, that the problem was a grave and complex one. The time had come for energetic, albeit, cautious action by the international community with a view to arriving at some solution."

The problem is grave and complex as the quality control of drugs concerns the identification of the product, the purity, the sterility, and also the importance of the study of toxic effects, and in addition, the process of packaging and labelling. An ideal solution may be difficult to arrive at and virtually impossible for the World Health Organization to control the manufacturing process in the various nations. Nevertheless, a few broad facts emerged: First, that the nations of the world were divided into three groups, those who manufacture drugs but did not export them; second, those who manufacture and export drugs; and third, those who do not manufacture and only import drugs. Moreover, the repeated plea from the developing nations, which by and large are the drug importing nations, was that the same level of quality should be required for the drug which was exported as for those destined for home consumption.

Dr. Otolorin of Nigeria, stated that the countries importing pharmaceuticals required *something positive to be done to protect these countries from malpractice.* He said that he, like the Delegate from Norway, was taken aback by the statement: "At the 19th World Health Assembly a suggestion was discussed for a system of certification to be evolved for drugs to be exported in order to ensure that they were subjected to the same quality control as applied to drugs for consumption in the exporting country. It was concluded that such a system did *not* appear feasible". Such a regulation may not be feasible for the World Health Organization to enforce but surely no more reasonable request was ever voiced by importing nations than that the drugs which were *exported* to them should be subject to the same measures of control as these drugs were for home consumption. Not only the Delegate from Nigeria voiced this request but also the Delegates from Senegal and from Spain. This was the repeated plea from the developing nations of the world.

The World Health Organization is not a police force and therefore such a regulation does not appear feasible for W.H.O. to enforce. Therefore, W.H.O. turned its attention to trying to set up a mechanism to help the importing nations test for the quality of drugs they import.

Furthermore, our government has offered to aid the drug importing nations in testing the quality control of the drugs they import. I quote from Dr. Blood's report (of U.S.P.H.) in which he reiterated "that wider national and international control of pharmaceutical products continue to be a matter of very great concern to our country. His government (i.e., the United States Government) had been and would continue to be ready to provide consultative technical assistance and training facilities to W.H.O. or any of its Member States in developing international standards and national codes for control, manufacture, processing, packaging or marketing of drugs. It was also prepared to provide certain testing services if some practical international system could be developed under the aegis of W.H.O.".

I am glad that the United States Government, through the U.S.P.H.S. has offered to help the drug importing nations to test their drugs. This approach to the problem is, however, unrealistic. The plain truth is that the countries which are too small to manufacture drugs or which have so recently emerged