

The official record of the World Health Organization, volume 157, the Executive Board of the 39th Session in Geneva, January 1967, on the quality control of pharmaceutical preparations:

Having considered the report of the Director General on the quality control of pharmaceutical preparations, noting that this matter has been the subject of repeated discussion at previous sessions of the Executive Board and the World Health Assembly;

Bearing in mind resolution WHA 18.36, which invited governments to take the necessary measures to subject pharmaceutical preparations, imported or locally manufactured, to adequate quality control;

Recalling particularly resolution WHA 19.47, requesting the Director-General to continue his assistance to member states for the improvement of the quality control of pharmaceutical preparations, and for the establishment of quality control laboratories for national or regional purposes, as well as the establishment of general principles for the quality control of products entering into international commerce;

Noting with concern that the requests of member states that drugs should not be exported without having been subject to the same quality control as those issued to the home market in the country of origin are not yet generally applied, and that in many cases pharmaceutical preparations are continuing to circulate without such control;

Noting, however, with appreciation, that certain member states are prepared—

And we are, too—

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 opened the discussion saying—

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.

Senator NELSON. I note from the Food and Drug Act that the only requirement that exists for the exportation of drugs from this country to foreign countries is that—

A food, drug, device or cosmetic intended for export shall not be deemed to be adulterated or misbranded under this Act if it, (1) accords to the specifications of the foreign purchaser, (2) is not in conflict with the laws of the country to which it is intended for export, and (3) is labeled on the outside with the shipping package to show that it is intended for export, but if such article is sold or offered for sale in domestic commerce, this subsection shall not exempt it from any of the provisions of this Act.

Now my question is this: If the requirement is that a drug exported from this country "accords to the specifications of the foreign purchaser and is not in conflict with the laws of that country," it seems to me that your criticism is well directed, since there probably are no underdeveloped countries in the world which have laws on the matter or have the expertise or competence to develop the laws. Further, they