

The Twentieth World Health Assembly,

Having considered the report of the Director-General on the quality control of pharmaceutical preparations;

Having noted resolution EB39.R8 of the thirty-ninth session of the Executive Board 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, but that desirable results have not yet been reached;

Bearing in mind resolution WHA18.36, which invited governments to take the necessary measures to subject pharmaceutical preparations, imported or locally manufactured, to adequate quality control;

Recalling particularly resolution WHA19.47, requesting the Director-General to establish generally acceptable principles for the quality control of pharmaceutical preparations, and to continue to assist Member States in their efforts to improve the quality control of pharmaceutical preparations and to establish quality control laboratories for national or regional purposes;

Noting with concern that the requests to 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; and

Considering the measures outlined in the Director-General's report on the improvement of the quality of drugs on the international level,

REQUESTS the Director-General:

- (i) to formulate as soon as possible principles for quality control procedures such as should be incorporated in good drug manufacturing practice;
- (ii) to continue work on analytical control specifications for international acceptance to be published as they are completed;
- (iii) to continue to assist Member States in establishing or securing access to national or regional laboratory facilities for quality control of drugs with support where appropriate of multilateral or bilateral assistance;
- (iv) to report to the Twenty-first World Health Assembly, through the Executive Board and with its comments, on the principles which should be included in regulations under Article 21 of the Constitution of WHO, supplemented, as may be necessary, by recommendations under Article 23, in regard to pharmaceutical products in international commerce and on the steps which the Organization would have to take to implement the programme of work involved;

(v) to ask again countries which export pharmaceuticals to ensure that these are subject to control measures which will secure that they comply with standards of quality not less than those imposed on domestic commerce; and

(vi) to report on the financial implications for WHO of any action proposed under this resolution.

Handb. Res., 8th ed., 1.3.2.1

*Eleventh plenary meeting, 23 May 1967 (Committee on Programme and Budget, sixth report)*