The Seventeenth World Health Assembly,

Having examined the report of the Director-General on the clinical and pharmacological evaluation of drugs;

Having noted resolution EB33.R21 of the Executive Board on the clinical and pharmacological evaluation of drugs;

Desirous of a rapid development of a rational programme by which WHO can contribute to the protection of man against hazards arising out of the medical use of drugs;

Appreciative of the assistance given in this respect by Member States, the Advisory Committee on Medical Research and the Section on Pharmacology of the International Union of Physiological Sciences; and

Convinced that international collaboration and co-ordination are indispensable for the achievement of such a programme,

1. INVITES all Member States:
   (1) to arrange to communicate to WHO any decision to refuse the approval of a new drug, or to withdraw or restrict the availability of a drug already in use as specified in resolution WHA16.36, in so far as they have not already done so, and to ensure that the justification for such action is communicated at the same time;
   (2) to develop, as quickly as possible, with a view to eventual international collaboration, their arrangements for the systematic collection and evaluation of information on serious adverse drug reactions observed during the development of drugs and, in particular, after their release for general use; and
   (3) to communicate to the Director-General the general principles and requirements which they consider essential for the evaluation of the safety and efficacy of drugs; and

2. REQUESTS the Director-General:
   (1) to continue to collect and disseminate decisions relating to adverse drug reactions as specified in resolution WHA16.36 and to report to the Executive Board if and when changes in these arrangements appear desirable;
   (2) to pursue, with the assistance of the Advisory Committee on Medical Research, and with a view to eventual international co-ordination, discussion on satisfactory methods for monitoring adverse reactions, especially late toxic effects, of drugs already in use; and
   (3) to undertake, with the assistance of the Advisory Committee on Medical Research, the formulation of generally acceptable principles and requirements for the evaluation of the safety and efficacy of drugs.

Eleventh plenary meeting, 17 March 1964 (Committee on Programme and Budget, fourth report)