The Sixteenth World Health Assembly,

Having noted the resolution of the Executive Board on the clinical and pharmacological evaluation of drugs; ²

Having examined the report by the Director-General on the clinical and pharmacological evaluation of drugs; ³

Considering that international co-operation is essential for the achievement of the best possible protection against hazards for man arising out of the use of drugs;

Agreeing to the definition of a “drug” as any substance, or mixture of substances, destined for use in the diagnosis, treatment, mitigation or prevention of disease in man, as set out in the report of the Study Group on the Use of Specifications for Pharmaceutical Preparations; ⁴

Realizing the technical and administrative difficulties of securing regular exchange of information on all drugs,

1. REAFFIRMS the need for early action in regard to rapid dissemination of information on adverse drug reactions;

2. REQUESTS Member States
   (a) to communicate immediately to WHO
      (i) any decision to prohibit or limit the availability of a drug already in use,
      (ii) any decision to refuse the approval of a new drug,
      (iii) any approval for general use of a new drug when accompanied by restrictive provisions, if these decisions are taken as a result of serious adverse reactions; and
   (b) to include in this communication as far as possible the reasons for the action taken and the nonproprietary and other names, and the chemical formula or the definition;

3. (a) RECOGNIZES the importance of accurate appraisal, at the national level, of the toxic effects of drugs; and
    (b) INVITES Member States to arrange for a systematic collection of information on serious adverse drug reactions observed during the development of a drug and, in particular, after its release for general use;

4. REQUESTS the Director-General
   (a) to transmit immediately to Member States the information received under paragraph 2;
(b) to study the value and feasibility, including the administrative and financial implications, of WHO collecting from and disseminating to Member States

(i) the non-proprietary and other names, chemical formulae and definitions of new drugs released or approved,

(ii) the information contained in 3 (b) above;

(c) to continue the study of the possibility of formulating, and of seeking international acceptance of, basic principles and requirements applicable to the toxicological, pharmacological and clinical evaluation of drugs; and

(d) to pursue action in the matter and report to the Executive Board and to the Seventeenth World Health Assembly.