ANNEX I
LABELING OF MEDICINES BASED ON STATUTORY INSTRUMENT No. 47 OF 1993

LABELLING OF MEDICINES

(1) Every package or container of medicine shall be labelled to show -
   (a) The name of the medicine;
   (b) The pharmacological properties;
   (c) The names and quantities of active ingredients;
   (d) The quality of the medicine;
   (e) The directions for use;
   (f) The contra-indications, warnings and precautions;
   (g) The storage instructions, when necessary;
   (h) The expiry date;
   (i) The batch number;
   (j) The date of manufacture;
   (k) The licence number;
   (l) The name and address of the manufacturer;
   (m) The method of sale, that is to say, if it is to be by:
      i. Prescription only;
      ii. Pharmacy sale only; or
      iii. General sale.

(2) When the space on the container of medicine is not adequate to accommodate the information specified in sub-paragraph (1), the container shall be labelled to indicate the particulars (a), (c), (d), (h) and (m) of sub-paragraph (l):

Provided that the particulars specified under paragraph (b), (e), (f), (g), (i), (j), (k) and (l) of sub-paragraph (1) shall be set out on the package.

(3) Where the container of medicine is in the form of a blister or strip packet, the container shall be labelled to indicate the particulars specified in paragraphs (a) and (m) of sub-paragraph (1) and the other particulars specified in that sub-paragraph shall be set out on the package.

(4) The provisions of this paragraph shall not apply to dispensed medicine:

(5) Every package or container of dispensed medicine shall be labelled to indicate-
   (a) The name of the person to whom the medicine is to be administered;
   (b) The dosage or where the medicine is to be used;
   (c) The date on which the medicine is dispensed; and
   (d) Any other information necessary to ensure the correct use of the medicine.

(6) A package or container of dispensed medicine may indicate the name and address of suppliers of the medicine.

(7) Where a package or container of dispensed medicine is to be administered to an animal, the package or container shall be labelled to indicate –
   (a) The name and address of the person in control of the animal;
   (b) Name and address of the suppliers of medicine;
   (c) The date on which the medicine is dispensed; and
   (d) Any other information necessary to ensure the correct use of the medicine.