11. LABELLING

The labelling of radiopharmaceutical preparations complies with the relevant national legislation and complies with the labelling requirements as per good manufacturing practices (GMP).

Apart from the general labelling requirements, the label on the direct container should state (1) that the product is radioactive in nature, (2) the name of the preparation and/or its reference, (3) the name of the manufacturer, (4) an identification number, (5) for liquid and gaseous preparations: the total radioactivity in the container, or the radioactive concentration per milliliter at a stated date and stated time, and the volume of liquid in the container, (6); (6) for capsules: the radioactivity per capsule at a stated date and time and the number of capsules in the container, and (7) route of administration.

The labelling can be adapted in certain cases (e.g. radiopharmaceutical preparations containing short-lived radionuclides).

The label on the outer package states, in addition to those on the direct container: (1) the route of administration, (2) the period of validity or the expiry date, (3) the name and concentration of any added antimicrobial preservative, and (4) where applicable, any special storage conditions.