

## EANM Reply to the EMA Consultation on the Union List of Critical Medicines

On behalf of the European Association of Nuclear Medicine (EANM), we have prepared a list of radiopharmaceutical products that we recommend for inclusion in the Union List of Critical Medicines, as previously circulated by the European Medicines Agency (EMA).

Please find attached the document containing our proposed additions. **We consider these products to be of fundamental importance for both diagnostic imaging and therapeutic applications in Nuclear Medicine**, and therefore believe they should be carefully evaluated for inclusion on the list.

Thank you in advance for your attention to this matter.

### List of Critical Medicines in Nuclear Medicine

#### 1.) Radionuclide Precursors:

[Yttrium Chloride for radiolabeling – Y90]

[Lutetium Chloride for radiolabeling – Lu177]

#### 2.) Radionuclide Generators

[Germanium/gallium generator – Ge68/Ga68]

[Molybdenum/technetium generator – Mo99/Tc99m]

#### 3.) Kits / final radiopharmaceuticals made from kits

[(human) Albumin macroaggregates – Tc99m]

[(human) Albumin nanocolloids – Tc99m]

[Bicisate (ECD) – Tc99m]

[Exametazime (HMPAO) – Tc99m]

[Mebrofenin (HIDA) – Tc99m]

[Medronate – Tc99m]

[Mertiatide (MAG3) – Tc99m]

[Oxidronate (HDP) – Tc99m]

[Pentetate (DTPA) – Tc99m]

[Sestamibi (MIBI) – Tc99m]

[Succimer (DMSA) – Tc99m]

[Sulfur colloids –Tc99m]

[Tetrofosmin – Tc99m]

[HYNIC-TOC-Tc-99m]

[Edotreotide- Ga68]

[Gozetotid (PSMA11)-Ga68]

#### **4.) SPECT radiopharmaceuticals**

[Oxine – In111]

[Pentetate (DTPA)– In111]

[Iobenguane (MIBG) – I123]

[(Sodium) iodide – I123]

[Ioflupane – I123]

#### **5.) PET radiopharmaceuticals**

[Fluorodopa – F18]

[Fluoro-deoxyglucose – F18]

[Fluoroethyltyrosine – F18]

[Fluoroestradiol – F18]

[Fluoro-PSMA ligands – F18]

[Flutemetamol – F18]

[Florbetaben – F18]

[Florbetapir – F18]

[Flortaucipir – F18]

[PSMA ligands – Ga68]

[Edotreotide (DOTATOC) – Ga68]

[Oxodotreotide (DOTATATE) – Ga68]

[DOTANOC – Ga68]

## **6.) Therapeutic radiopharmaceuticals**

[Microspheres glass – Y90]

[Microspheres resin – Y90]

[Yttrium citrate colloids – Y90]

[(Sodium) iodide – I131] capsules and solution

[Iobenguane (MIBG) – I131]

[Lutetium PSMA ligands – Lu177]

[Lutetium DOTATATE – Lu177]