GOVERNMENT OF INDIA
DEPARTMENT OF ATOMIC ENERGY
RAJYASABHA
UNSTARRED QUESTION NO – 962
ANSWERED ON 13/02/2025

RADIATION TECHNOLOGY AND RADIO-PHARMA PRODUCTS

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Will the PRIME MINISTER be pleased to state:-

(a) whether it is a fact that radiation technologies are useful in the field of medicine and health care;
(b) if so, in what ways radiation technologies are useful in the field of medicine and health care;
(c) whether any new radio-pharma products developed/launched by the Department since 2019;
(d) if so, the details of all the radio-pharma products developed/launched by the Department since 2019;
(e) whether any steps taken by the Department towards indigenization of radio-pharma products and their commercialization; and
(f) if so, the details thereof?

ANSWER

THE MINISTER OF STATE FOR PERSONNEL, PUBLIC GRIEVANCES & PENSIONS AND PRIME MINISTER'S OFFICE (DR. JITENDRA SINGH)

(a) & (b). Yes, radiation technologies play a significant role in various aspects of modern human healthcare namely prevention, diagnosis and therapy. The radiation technology can be used for sterilization of medical products, organ function evaluation, diagnosis and therapy of diseases like cancer.

Radiation sterilization of medical products is an effective method of prevention of diseases, as it completely avoids cross-contamination through de-activating the

pathogenic organisms. Radio-isotope ^{137}Cs in non-dispersible form is also used in blood irradiator.

Radiopharmaceuticals are radioisotope tagged medical formulations which are safe for human administration and used for the non-invasive diagnosis and therapy of various diseases including cancer. These radio-isotopes are produced in research reactors, particle accelerators such as cyclotrons or extracted from radio-active waste. Some of the radio-isotopes formulations such as Technetium-99m labelled agents are used for detection of various human diseases and extensively used in cardiology, nephrology, oncology etc. Iodine-131 in the form of sodium iodide is used for diagnosis and therapy of thyroid-related disorders, lutetium-177 labelled agents are used for therapy of neuroendocrine and prostate cancers.

The short lived radioisotopes having suitable radiation properties as well as chemical properties are used in the form of radiopharmaceuticals for disease diagnosis and treatment. Radiopharmaceuticals are special radiochemical formulations in which the radioisotope is tagged to a suitable carrier molecule and ascertained to be safe for administration in humans. While technetium-99m (Tc-99m), fluorine-18 (F-18) and Gallium-68 (ga-68) in the form of radiopharmaceuticals are used for disease diagnosis, beta radiation emitting radioisotopes such as Lutetium-177 (Lu-177), Iodine-131 (I-131), Yttrium-90 (Y-90) etc. are employed for cancer treatment. Cobalt-60 (Co-60) sealed sources which emit high energy gamma radiations are used for teletherapy (cancer treatment) while Iridium-192 (Ir-192), Iodine-125 (I-125) and Ruthenium-106 (Ru-106) based sealed sources are used for brachytherapy towards treatment of cancers such as that of the eye, cervix, prostate etc.

Other radiation technologies for cancer treatment includes Brachytherapy and Teletherapy. Brachytherapy is a form of internal radiation therapy used primarily to treat cancer where radioactive sources are placed directly inside or very close to the tumour to deliver radiation dose while minimizing exposure to surrounding healthy tissues. It is commonly used for cancers of the prostate, breast, cervix, eye and skin. Brachytherapy offers a highly precise method for controlling tumour growth while reducing side effects. Bhabha Atomic Research Centre (BARC) a

constituent Unit of Department of Atomic Energy (DAE) has developed iodine-125-ocuprosta seeds used for therapy of eye cancer and prostate cancer. Another Brachytherapy source developed in BARC is Ru-106-eye plaque for treating eye cancer.

Teletherapy is another radiation technology wherein high-energy gamma-rays are directed at a tumour from outside the body using an external radiation source such as cobalt-60. Teletherapy is commonly used for treating various types of cancer, including those of the brain, breast, lung, and prostate. Bhabhatron is a teletherapy machine developed in DAE.

There is significant availability of Nuclear Medicine facilities in the country in Government and Private sector. There are more than 500 such facilities available now. In all of them Diagnostic and Therapeutic nuclear medicine can be practiced. High dose radioiodine therapy needs special additional facilities which are offered in more than 100 centres. Single Photon Emission Computerized Tomography – SPECT, Positron Emission Tomography – PET, Computerized Tomography – CT are the devices through which Diagnostic Nuclear Medicine is practiced. It helps in Staging, restaging, response evaluation of cancer. 18 F FDG, 18 F DOPA, 68Ga DOTA NOC are some commonly used PET Radiopharmaceuticals. 99mTC MDP, MIBI, Mebrofenin, DTPA, EC and 131Idoine are common Radiopharmaceuticals for SPECT studies. Radioiodine-131I, 177 Lutetium DOTA TATE, 177 Lutetium PSMA, are common nuclear Medicine therapies for cancer patients. As an example, under Tata Memorial Centre (DAE), Department of Nuclear Medicine at Homi Bhabha Cancer Hospital and Research Centre, New Chandigarh is a state of the art Theronostic facility. Theronostic means a facility containing both diagnostic and therapeutic services.

Gamma Camera and its associated radiopharmacy lab: This unit is equipped to perform multiple types of functional imaging helping with cancer staging with scans such as 99mTc PSMA etc. other imaging services help with assessing the function such as MUGA imaging to assess cardiac function etc.

PETCT and its radiopharmacy lab: This unit primarily works for cancer staging, most commonly used radioactive pharmaceutical is 18F FDG which is used in

majority of cancers for staging such as for evaluation of carcinoma lung, carcinoma esophagus, breast cancer, lymphoma, etc.

Radioactive Pharmaceuticals such as Ga68 DOTANOC, Ga68 FAPI (All prepared and quality checked in house) are utilized for evaluation of various cancers (such as prostate cancer, Neuroendocrine Tumors, Mucinous and Signet GI cancers etc.)

High dose Radionuclide therapy ward and its radiopharmacy lab: 6 bedded high dose therapy ward has been designed as per the Atomic Energy Regulatory Board (AERB) guidelines with appropriate layout and provision of a delay tank to contain radioactive sewage for proper disposal of contaminated patient sewage.

Additionally, 41 Radionuclide Therapy beds have also been commissioned as per AERB guidelines in the Advanced Centre for Treatment, Research and Education in Cancer (ACTREC), Tata Memorial Centre in Kharghar, Navi Mumbai. 1311Nal is utilized for treatment of thyroid cancer, Lu177 PSMA and Lu177 DOTANOC for management of prostate cancer, neuroendocrine cancer and other SSTR expressing malignancies.

(c) & (d). Yes, Department of Atomic Energy has developed and launched several radio-pharma products since 2019. Department has been working towards ensuring uninterrupted supply of radioisotopes and radiopharmaceuticals in the country. While constantly carrying out research to develop new radiopharmaceuticals for cancer care, DAE has also achieved indigenization of clinically established radiopharmaceuticals and allied products at an affordable cost.

The following radiopharmaceuticals indigenously developed since 2019 are available on demand through the Board of Radiation and Isotope Technology (BRIT), an Industrial Unit of DAE:

Sr. No.	Product description	Use/applications
1.	^{90}Y-labeled hydroxyapatite (HA)	Radiation synovectomy
2.	^{177}Lu-labeled hydroxyapatite (HA)	Radiation synovectomy
3.	^{177}Lu-DOTA TATE	Therapy of neuroendocrine tumors

Sr. No.	Product description	Use/applications
4.	^{177}Lu-DOTA-TRASTUZUMAB	Breast cancer expressing HER-2 receptors
5.	Clinical grade NCA Radiochemical copper-64 chloride ($^{64}CuCl_2$)	PET imaging of cancer/ radiochemical for ^{64}Cu-RPh preparation
6.	^{177}Lu-DOTMP	Bone pain palliation
7.	^{90}Y-GLASS MICROSPHERES	Liver cancer therapy
8.	^{188}ReN-DEDC/Lipiodol (improved method)	Liver cancer therapy
9.	^{177}Lu-CHX-A"-DTPA-Rituximab	Therapy of non-Hodgkin's lymphoma
10.	Copper-64 chloride ($^{64}CuCl_2$)	PET imaging of cancer
11.	^{99m}Tc-HYNIC-[cycle(RGDfk)]$_2$	Imaging of malignant tumor
12.	^{177}Lu (Lutetium)-PSMA-617 injection	Prostate cancer therapy
13.	^{99m}Tc (Technetium)-based HYNIC-RGD Kit	Tumor Angiogenesis Imaging
14.	^{177}Lu (Lutetium)-HA	Radiation Synovectomy of small joints
15.	^{90}Y (Yttrium)-HA	Radiation Synovectomy of big joints
16.	^{68}Ga(Gallium)-DOTA-TATE	PET imaging of Neuroendocrine tumors
17.	^{68}Ga(Gallium)-PSMA-11	PET imaging of Prostate Cancer
18.	Fission ^{99}Mo (Molybdenum)	Precursor radionuclide for producing 99mTc for SPECT radiopharmaceuticals
19.	^{90}Y (Yttrium)-Bhabhasphere	Liver cancer therapy
20.	NCA (No carrier added)-^{177}Lu-PSMA-617 injection	Prostate cancer therapy
21.	NCA (No carrier added)-^{177}Lu-DOTA-TATE injection	Neuroendocrine tumor therapy

The following radiopharmaceuticals are produced and have been initiated on trial basis at the Medical Cyclotron Facility at Variable Energy Cyclotron Centre (VECC), Kolkata, a constituent unit of DAE:

- PET radiopharmaceutical, Copper-64-Chlodide (for Therapy + Diagnostic of cancer) produced on trial basis from solid target of Zinc-68.
- SPECT radioisotope Iodine-123 (for Diagnostics of thyroid cancer) produced on trial basis from solid target of Tellurium-124.
- Germanium-68/Gallium-68 generator produced on trial based from solid target of Gallium-Nickel alloy electroplated target. It will minimize import cost of generator.
- SPECT radioisotope Lead-203 (Pb-203) (for imaging and also cancer therapeutic applications) produced, first time in India, on trial basis from low cost natural thallium target.

(e) & (f). DAE is putting significant efforts towards indigenous development of radiopharmaceuticals and allied products for availability of cost-effective alternatives to imported radiopharmaceutical products. These efforts are enhanced through collaborations both within the DAE and through collaborations with Institutes and leading nuclear medicine centers such as All India Institute of Medical Sciences (AIIMS), Postgraduate Institute of Medical Education and Research (PGIMER), Chandigarh, Jawaharlal Institute of Postgraduate Medical Education & Research (JIPMER), Pondicherry through Board of Research in Nuclear Sciences (BRNS) funded projects.

The commercialization of radiopharmaceuticals and allied products developed in DAE is realized through BRIT.

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