



PHARMACEUTICALS EXPORT PROMOTION COUNCIL

(Set up by Ministry of Commerce, Govt. of India)

COPY

Date : 08-07-2010

News / Story reproduced with thanks:- **Pharmabiz**

IPC to add monographs of radiopharmaceuticals in IP soon

Thursday, July 08, 2010 08:00 IST

Gireesh Babu, Mumbai

Direct link to the News/Story:-

<http://www.pharmabiz.com/article/detnews.asp?articleid=56294§ionid=>

The Indian Pharmacopoeia Commission (IPC) has initiated efforts to include radiopharmaceuticals, used in the field of nuclear medicine, as tracers in the diagnosis and treatment of various diseases including cancer, in the Indian Pharmacopoeia for the first time.

The plans are to add a general chapter and about 25 monographs of radiopharmaceuticals which are widely used for diagnostic and therapeutic use in India in the initial stage. The commission has formed an expert committee consisting of eminent scientists from the field, chaired by professor Rakesh Kumar Sharma, head, Chemical Biological Radiation and Nuclear Defence (CBRN) Institute of Nuclear Medicines and Allied Sciences (INMAS) under the Defence Research & Development Organisation (DRDO), to prepare the general chapter and monographs.

According to IPC sources, the expert committee which had its first meeting in the beginning of this month, has agreed for adding almost 25 monographs and the committee is expected to complete its job within a period of six months.

The list of radiopharmaceuticals identified for monographs includes F 18, sodium fluoride injection, flurodeoxyglucose (18F) injection, iobenguane [131I] injection for diagnostic use, iobenguane [131I] injection for therapeutic use, samarium ethylene diamine tetramethylene phosphonate complex (153Sm) injection, sodium iodide [131I] capsule for diagnostic use, sodium molybdate [99Mo] solution (+ n-gamma), sodium molybdate [99Mo] solution (Fission), sodium pertechnetate (99Tc) injection, sodium phosphate (32P) injection and several radiopharmaceuticals based on Technetium (99mTc).

The effort of IPC is to keep pace with emerging and contemporary areas for addressing the issues of healthcare requirements, in tandem with the regulatory developments in global pharma sector, said a senior scientific officer from the Commission.

The radiopharmaceuticals, which are the drug formulations containing radioisotopes and are suitable for administration in humans for diagnosis and therapy of various disease states, are already included in advanced pharmacopoeias in developed countries. The World Health Organisation (WHO) has also provided more importance to the radioisotopes in its International Pharmacopoeia, of late. The IPC's efforts to address the segment is to keep the Indian Pharmacopoeia on par with these standards, said the source.

The general chapter and monographs will be published most probably in the Addendum of IP-2010, which will be out in 2011 or in the next edition of pharmacopoeia, depending on the duration taken for finalising the technical matters related, he added.