15. hafta

Radyofarmasötiklere ait yasal düzenlemeler

European Medicines Agency
Inspections

London, 26 November 2008
Doc. Ref. EMEA/CHMP/QWP/306970/2007

COMMITTEE FOR HUMAN MEDICINAL PRODUCTS
(CHMP)

2. SCOPE

This guideline covers the following products:

- ready-for-use radiopharmaceuticals, including PET radiopharmaceuticals;
- non-radioactive components (kits and chemical precursors including those for positron emission Tomography) for combination with a radioactive component (e.g. eluate from a radionuclide generator or a cyclotron produced radionuclide);
- radionuclide generators;
- radionuclide precursors used for radiolabelling other substances prior to administration.

Article 3.5 of Directive 2001/83/EC specifically mentions radionuclides in sealed sources as being outside the requirements of the Directive, and therefore outside the scope of this guideline.

Australian Government

Department of Health

Therapeutic Goods Administration

Guidance 20: Radiopharmaceuticals

Previously ARGPM Appendix 20: Supplementary guidelines for radiopharmaceuticals

Version 1.0, July 2013

Guidance for Industry

Developing Medical Imaging Drug and Biological Products

Part 1: Conducting Safety Assessments

Additional copies of this Guidance are available from:

Division of Drug Information HFD-240
Center for Drug Evaluation and Research
Food and Drug Administration
5600 Fishers Lane, Rockville, MD 20857
(Phone 301-827-4573)
Internet: http://www.fda.gov/cder/guidance/index.htm.

II. SCOPE — TYPES OF MEDICAL IMAGING AGENTS

This guidance discusses medical imaging agents that are administered in vivo and are used for diagnosis or monitoring with a variety of different modalities, such as radiography, computed tomography (CT), ultrasonography, magnetic resonance imaging (MRI), and radionuclide imaging. The guidance is not intended to apply to the development of in vitro diagnostic or therapeutic uses of these agents.[2]

Medical imaging agents can be classified into at least two general categories, contrast agents and diagnostic radiopharmaceuticals.

Radiopharmaceuticals

Work Description	:	Guidelines for basic requirements for registration of Radiopharmaceuticals. These Guidelines are intended to complement those already available for pharmaceutical products as well as those for sterile pharmaceutical products.
Based On	:	International Atomic Energy Agency (IAEA), Guidelines for Good Manufacturing Practices for Radiopharmaceuticals, 2001. WHO, Guidelines for Good Manufacturing Practices for Radiopharmaceutical Products, Annex 3, 2003. US FDA, Guidance for Industry, Nonclinical Evaluation of Late Radiation Toxicity of Therapeutic Radiopharmaceuticals, June 2005. European Association of Nuclear Medicine (EANM), Guidelines on Current Good Radiopharmacy Practice (cGRPP) In the Production of Radiopharmaceuticals, May 2006.

Document QAS/08.262/FINAL
November 2008

World Health Organization

RADIOPHARMACEUTICALS

Final text for addition to *The International Pharmacopoeia* (November 2008)

This text was adopted at the Forty-third WHO Expert Committee on Specifications for Pharmaceutical Preparations in October 2008 for addition to the 4th edition of The International Pharmacopoeia.

WHO Technical Report Series, No. 908, 2003

Annex 3
Guidelines on Good Manufacturing Practices for radiopharmaceutical products