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Clinical Trials for = Radiopharmaceuticals in Brazil.

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Introduction

For quite a long time, radiopharmaceuticals in = Brazil have=20 been exempted from adopted pharmaceutical regulation.=20 Applicable rules were on radiation protection and = compliance=20 to Pharmacopoeia monographs. In 2009 the Regulatory = Agency=20 (ANVISA) published the RDC 63 and 64 extended the = existing=20 rules of medicinal products to radiopharmaceuticals = compounds=20 used as diagnostic or therapeutic agents.

Objective

The aim of this work is to give an overview of the=20 situation of clinical trials for radiopharmaceuticals = in=20 Brazil, Europe and USA.

Results and Discussion

The immediate consequence of the new regulations = for the=20 principal radiopharmaceutical producer in Brazil = (IPEN/CNEN),=20 was the need to file a registration of = radiopharmaceutical=20 products that have been on market for a long time. A = shortened=20 procedure was accepted by ANVISA a single file of=20 pharmacological, toxicological and clinical support = using=20 available data or published literature was judged as=20 appropriate for the 38 radiopharmaceuticals products. = On the=20 other hand, for the new radiopharmaceuticals products = it is=20 necessary running all expected protocols, including=20 preclinical and clinical trials that would require not = only=20 years but a huge financial Brazilian government = support and an=20 appropriate separated regulation for = radiopharmaceuticals. In=20 Brazil the pharmaceutical regulations for clinical = trials have=20 been kept as unique code, focused on conventional = medicinal=20 products and there are no separated

regulations for = special=20 situations such as that of radiopharmaceuticals. = Europe has=20 been established regulatory issues for = radiopharmaceuticals as=20 described in Directive 2001/20EC and Directive = 2003/63/EC. In=20 the Directive 2003/63/EC Module 3 and 4 refer that is=20 important to evaluate de radiation dosimetry aspects = moreover=20 the results of clinical trials shall be provided where = applicable otherwise justified in clinical overviews. = However,=20 it is important to note that the guidelines for = clinical=20 trials in Europe refer only to radiopharmaceuticals = used for=20 diagnostic procedures. In United States the regulatory = issues=20 for radiopharmaceuticals are established in 1975 and = the FDA=20 and NRC determined that all radiopharmaceuticals are = drugs and=20 all human studies must be carried out under an = Investigational=20 New drug (IND) or radioactive drug research committee = (RDRC)=20 protocol. The Code of Federal Regulations Title 21 Sec = 312.20=20 specifies that if the drug is a radioactive drug the = phase I=20 studies must include studies which will obtain = sufficient data=20 for dosimetry calculations. In 2006 the FDA releases = the=20 exploratory IND guidance to provide a lower threshold = for=20 radiopharmaceutical and candidate drug first in human = studies,=20 using the microdosing concept that may not be = conducted under=20 a RDRC protocols. In conclusion, the obstacles to the=20 introduction of new radiopharmaceuticals are = significant and=20 Brazilian regulatory documents to clinical trial with=20 radiopharmaceuticals are needful.=20

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