SAMIRA CONFERENCE – SESSION 2 (Dr. Schiavo's talk – summary)

In the view of the Radiopharmaceuticals Drafting Group of the European Medicines Agency, there are many barriers to the market introduction of new medical applications using radionuclides. During the conference, six of these barriers ways to address them were exposed:

BARRIER 1.- There is a lack of uniformity in the National regulation of the Member States regarding the production and use of some radiopharmaceuticals without marketing authorization, mostly PET radiopharmaceuticals. Harmonization of regulation by authorities in the EU concerning production and use of radiopharmaceuticals is necessary.

BARRIER 2.- The rapid introduction in clinical practice of experimental radiopharmaceuticals alternative to those which have followed all the pathway to get a marketing authorisation in the EU is a problem. In this situation, those companies producing radiopharmaceuticals are not so sensitive to apply for marketing authorisation.

BARRIER 3: Guideline on clinical evaluation of diagnostic agents bases the efficacy of a diagnostic radiopharmaceutical mostly in adequate sensitivity and specificity. Nowadays demonstration of the impact on diagnostic thinking and/or therapeutic management and/or clinical outcome is becoming more important for clinical practice. The guideline on clinical evaluation of diagnostic agents should be updated requiring demonstration of the impact of radiopharmaceuticals on the making decision process as a priority, and requiring the analysis of the "added value" of the radiopharmaceutical for the patient.

BARRIER 4: Concerning orphan radiopharmaceuticals, companies are requesting marketing authorisation when they have already being used in European countries for a long time, and sometimes without presenting own clinical trials but a review of published literature to base their efficacy.

BARRIER 5: Guideline on the quality evaluation of generic radiopharmaceuticals does not exist in Europe. Regulatory guidance by a guideline dealing with the quality aspects of generic radiopharmaceutical is necessary.

BARRIER 6.- Some therapeutic radiopharmaceuticals have been developed for oncological treatment of a particular indication but without direct comparative data versus the chemoterapeutic treatments already used when the radiopharmaceutical is marketed.

Finally it should be remarked that, although research goes faster than regulatory affairs and rules may become barriers, the temptation of deregulating radiopharmaceutical production should be avoided.