The Royal Liverpool and Broadgreen University Hospitals NHS Trust

Royal Liverpool University Hospital
Prescot Street
Liverpool
L7 8XP

Radiopharmacy Department

U.K. Radiopharmacy Group

Direct line: 0151-706-4521
Direct fax: 0151-706-4522
E-mail: paul.maltby@rlbuht.nhs.uk

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Mr Stefan FUEHRING,
EUROPEAN COMMISSION
ENTERPRISE AND INDUSTRY DIRECTORATE-GENERAL
Consumer goods
Pharmaceuticals

e-mail address: Stefan.FUEHRING@ec.europa.eu

Dear Mr Fuehring.

ASSESSMENT OF THE FUNCTIONING OF THE "CLINICAL TRIALS DIRECTIVE" 2001/20/EC
PUBLIC CONSULTATION PAPER

I am writing on behalf of the UK Radiopharmacy Group.

We wish to draw to your attention for consideration during the review of this Directive an issue relevant to Consultation item n°9: in section 5 (page 21-24) which relates to the fact that the requirements of the CTD are the same for all clinical trials irrespective of the inherent risk.

This statement is counter-intuitive, as all clinical activity involving medicines whether licenced, unlicenced or of clinical trial origin is based on risk assessments made in the light of the known and perceived pharmacological profile of the product. We believe that the risk in clinical trials using diagnostic radiopharmaceuticals (for both imaging and non-imaging studies) is very much less than that for therapeutic products as the total mass of the substance present is insufficient to cause a direct pharmacological response, they are used for 1-2 administrations only, and are given solely under direct specialist hospital supervision Thus they should be given a lighter regulatory touch.

Secondly, we believe that the status of academic trials not used as part of filing for drug registration purposes (but of which underpins the decision making process to progress for this procedure) must be separated as these crucial trials are being stifled (see for example Langstrom B & Hartwig P Eur J Nucl Med Mol Imaging (2008)35:693-694).

We would ask that academic trials should be required to submit a greatly reduced application which provide a more limited but sufficient justification on the grounds of a) safety (both pharmacological and toxological) and b) scientific robustness. If this general principal is accepted by EU/EMEA we would be very happy to help to identify the requirements that should be either deleted or reduced and develop appropriate requirements.

Yours sincerely,

Paul Maltby CSci MIPEM MRPharmS

Chief Radiopharmacist
Chair of UK Radiopharmacy Group