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

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Dear Mr Fuering,

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

I am writing on behalf of the British Nuclear Medicine Society.

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.

The proposal is that the system should be changed to take account of the risk. 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 (single administration, no pharmacology, hospital supervision etc) and they therefore should require a lighter regulatory touch.

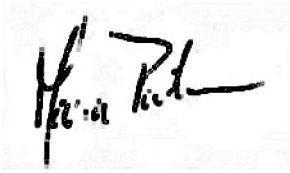
Our wish to see relaxation/exemption for Radiopharmaceuticals is on two grounds – firstly the very low risk to the subject involved in radiotracer studies – 1 or 2 non-pharmacological doses delivered to patients with known disease under medical supervision in hospitals with a known quantifiable risk from the radiation dosimetry.

Secondly, the status of academic trials that are not being used as part of a drug registration process. This is important because much of the information that has currently to be supplied in a CTA is justified because this is ultimately used to support the final drug registration process and currently represents an unreasonable burden on academic researchers.

Relaxation of this regulatory burden is urgently needed because the current highly restrictive system is having a profoundly negative effect on academic trials (e.g. See recent letters from Langstrom et al in EJNM) and also there is a need for more

biomarker studies to support developments in Molecular targeted therapies.

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.



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