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Association of Imaging Producers and Equipment Suppliers
(Nuclear Medicine and Molecular Healthcare)

To the attention of:
DG Enterprise and Industry – Pharmaceuticals Unit
entr-pharmaceuticalscounterfeit@ec.europa.eu

Brussels, 31 July 2008

Subject: **Public consultation in preparation of legal proposal to combat counterfeit medicines for human use – Key ideas for better protection of patients against the risk of counterfeit medicines**
Application to radiopharmaceuticals

- **What is AIPES?**

The Association of Imaging Producers and Equipment Suppliers (AIPES) is a European Economic Interest Grouping (EEIG) based in Brussels, which represents the interests of the major nuclear medicine tracer companies as well as the equipment manufacturers and contrast media manufacturers established in the European Union. It is composed of both multinational companies and Small and Medium Enterprises (SMEs).[1] The members of the association are listed here below:

- AAA (Advanced Accelerator Applications)
- Biokosmos
- Bioscan
- BMS Pharma (Brystol-Myers Squibb)
- CIS Bio International
- Covidien
- Cyclopharma
- GE Healthcare
- Iason
- IBA (Ion Beam Applications)
- Lemer Pax
- MAP Medical Technologies
- MDS Nordion
- Philips Medical Systems
- Siemens Medical Solutions
- Skyscan

[1] http://www.aipes-eeig.org

- **AIPES' position on the Commission's proposal**

On 11 March 2008, DG Enterprise and Industry (Pharma Unit) launched a public consultation on counterfeiting in order to prepare a legislative proposal to combat the counterfeiting of medicines for human use.

The deadline for this consultation was 9 May 2008. AIPES has thus clearly missed the comments deadline.

However, after reading the proposal and the comments which were sent (notably by EFPIA), AIPES believes that it is important to inform DG Enterprise about its position:

AIPES appreciates this initiative, which aims to protect both patients against the risk of counterfeit medicines and innovative enterprises. However, AIPES believes that some of the proposals are not adapted to radiopharmaceutical medicinal products, notably because those products are already submitted to very strict rules.

AIPES is particularly concerned with possible requirements for seals on outer packaging and traceability through the supply chain. In this regard, AIPES believes that radiopharmaceuticals should not be included in any new tracking process for the reasons given below.

Indeed, regulations governing the supply chain for radioactive products are already sufficiently strict. Any further regulations would be unnecessary. The same can be said regarding seals on outer packaging. Radioactive radiopharmaceuticals are subject to stringent international regulations governing the shipment of radioactivity. These products may only be despatched to authorised individuals who are licensed to receive and use such products. Manufacturers are required to check that customers are properly licensed before radiopharmaceuticals are despatched. Therefore strict controls are already in place to address security of shipment. In addition, radioactive radiopharmaceuticals have very short shelf lives because of the decay of radioactivity, and rapid shipment to the end user is necessary; hence these products are not held in warehouses for extended periods or handled by many different individuals during transport, unlike 'traditional' medicinal products may be.

Therefore, AIPES believes that radiopharmaceutical medicinal products should be considered as a unique class of products for which it would serve no purpose to apply stricter requirements for seals on outer packaging and traceability through the supply chain.

Therefore, AIPES requests that radiopharmaceuticals should be exempted from the scope of the new proposal under preparation at the level of the European Commission.

We very much hope that you will agree with our proposed solution.

We remain at your disposal in order to discuss the issue further.

On behalf of AIPES
Gerhard Vollberg (Head of Regulatory Affairs)
Jean-Luc Laffineur (Lawyer)