EANM EXECUTIVE OFFICE
Schmalzhofgasse 26 | 1060 Vienna | Austria

+43 1 890 44 27
office@eanm.org
www.eanm.org

The European Association of Nuclear Medicine (EANM) appreciates the opportunity to comment on the European Medicines Agency's (EMA) policy on handling competing interests among scientific committees' members and experts.

EMA's commitment to balance securing the best scientific expertise with impartiality is commendable and should be further pursued. The EMA is renowned for its impartial scientific assessments of medicines, weighing their clinical benefits against potential risks. This reputation hinges on a transparent and detailed conflict of interest policy. EMA's handling of competing interests must balance its legal obligations: ensuring that committee members and experts do not have conflicts of interest with pharmaceutical companies that could compromise their impartiality, while still securing the best scientific expertise.

While EANM strongly supports a robust framework for managing competing interests with thorough restrictions on experts' involvement with industry, this must be done proportionately to avoid limiting EMA's access to top-tier experts. The scientific community is concerned that the new EMA policy on handling competing interests might restrict access to scientific excellence. In nuclear medicine, as in many specialties, key experts and opinion leaders are at the forefront of innovation, engaged in fundamental research, and supported by various grants. They are best positioned to provide valuable input and expertise to the EMA.

More specifically, the EANM, representing healthcare professionals involved in research organisations, would like to comment on some indirect links as mentioned on *Annex 3 –Handling of current and past interests in research organisations*.

Most radiopharmaceuticals have a very short shelf life and therefore need to be prepared extemporaneously in-house, e.g. in the institution so that they can be used within minutes or hours after preparation, to avoid that they lose their radioactive potentials by physical decay. In that respect, we would very much welcome a clarification of the *„involvement in a unit that manufactures medicinal products or medical devices "*. Indeed, this declared interest in a research organisation does suit the nuclear medicine ecosystem, as in that respect, all the professionals working in a research organisation having its own cyclotron (which is the case for most leading research organisations in Europe) would be excluded from interacting with EMA.
We therefore invite the European Medicines Agency to differentiate between manufacturing of medicinal products to put in the market and medicinal products to be used by the producing institution.

Additionally, a second clarification would be welcomed regarding *„Involvement in the conduct of research and development activities together with a company."* To ensure that experts from leading research centres in Europe and those performing fundamental research can contribute to meaningful EMA discussions, the nuclear medicine community would call the EMA to distinguish between "involvement in the conduct of research and development activities funded by a research grant for fundamental research supported by the industry" and the "involvement in the evaluation of products directly with a company". This would ensure that leading experts involved in fundamental research can continue contributing to EMA discussions on innovative matters.

Finally, the EANM would like to emphasize that some further clarification would also be needed on grant or other funding to the expert's organisation/institution (section 3.2.2.2). Therefore, experts supporting services activities as performed routinely in clinical practice, should be excluded from this category, provided that the expert is not the main recipient of the grant.