

Integrating Nuclear Medicine Europe into the Framework of the Critical Medicines Alliance

By Mart-Jan Blauwhoff

president Nuclear Medicine Europe

Nuclear Medicine Europe is a centralised association that brings together professionals, researchers and industry representatives to advance nuclear medicine across Europe. By fostering collaboration, sharing best practices, and advocating for regulatory and policy support, Nuclear Medicine Europe enhances the visibility and impact of nuclear medicine in healthcare. Through its initiatives, Nuclear Medicine Europe not only champions innovation but also strives to ensure that the benefits of nuclear medicine are accessible to all patients, reinforcing its essential role in modern medical practice.

Nuclear medicine is a vital and rapidly advancing field that plays a crucial role in the diagnosis, treatment, and management of various medical conditions, particularly cancer and cardiovascular diseases. Utilizing small amounts of radioactive materials, nuclear medicine provides unique insights into the functioning of organs and tissues, enabling healthcare professionals

to tailor treatments to individual patients. As this specialty continues to evolve, the importance of collaboration and advocacy within the industry cannot be overstated.

Nuclear Medicine diagnoses and treats an estimated 30 million patients worldwide using radiopharmaceuticals. Drugs that contain a radioactive molecule allowing functional imaging and therapy of most organs with a minimum of adverse events due to the low amount of active substance. Nuclear Medicine has a dual governance, on one hand pharmaceutical legislation and on the other hand radiation safety regulations which are sometimes contradicting.

Radiopharmaceuticals are special since due to the half-lives of between ~1 hour and 8 days of the contained isotope they have no shelf life. Meaning what is ordered today is often produced and shipped within 24 hours and used in hospitals around the world upon arrival. Any delays make it most of the time unusable.

What is the position of Europe in the production of radiopharmaceuticals?

Europe is the leading world supplier of medical radioisotopes and a leader in developing nuclear medicine diagnostics and treatments. As an example: Tc99m is the most used isotope for around 80% of diagnostic procedures in nuclear medicine. With 4 of the 6 main research reactors and 2 largest producers of the mother isotope Mo99 located in the EU, Europe plays a global role in the production of Technetium generators and Iodine 131 for therapy. With other therapeutic isotopes playing a more prominent role the importance of having a fleet of reactors is even more important. The downside is that the current reactors are up to 60 years old and new ones are being built but these are not expected to be online before 2030. Isotope production methods not using reactors are in planning and will add additional capacity.

The increasingly important role of therapeutic treatments.

Nuclear medicine treatments are available and complementary to other cancer treatments. Contrary to many pharmaceutical or radiotherapy treatments nuclear medicine delivers radiation directly to the tumor cells with very limited side effects to other tissues. This is one of the reasons why Nuclear Medicine is the only medical specialism that is specifically mentioned as an essential treatment in the EU Commissions' Beating Cancer plan. (<https://nuclearmedicineeurope.eu/wp-content/uploads/2022/07/What-is-nuclear-medicine-and-how-can-it-help-Europe-beat-cancer.pdf>)

What are the four main challenges facing Europe's nuclear medicine sector?

- Raising awareness and understanding of nuclear medicine's benefits with healthcare professionals, patients and the general public.
- Regulation that adapts to the specificities of radiopharmaceuticals for marketing authorisations, product registration, preparation, transport/delivery and radioprotection.
- Support for innovation and technical development across the EU, through training and certification of healthcare professionals and equipment so all EU citizens can access the full benefits of nuclear medicine with equal opportunity.
- Secure and reliable supply for current and future radioisotopes for both therapy and diagnosis, grounded in resilient European infrastructures.

Also financial issues are a threat to availability of radiopharmaceuticals.

Due to countries subsidizing the operation of reactors they were keeping radiation cost for medical isotopes low, in fact supporting nuclear medicine across the world. In compliance with OECD/NEA HLG-MR policy, full-cost recovery and outage reserve capacity mechanisms for the Mo-99 supply principles as well as conversion from highly enriched uranium (HEU) to low-enriched uranium (LEU) for medical isotope production were introduced which has led to considerable cost increase for the production of this essential isotope for nuclear medicine. ([The Supply of Medical Radioisotopes: An Economic Study of the Molybdenum-99 Supply Chain. OECD 2010](#)). Adding inflation and additional GMP, regulatory requirements as well as cost increase due to radiation safety or non-proliferation regulations are impossible to fully cover for industry as reimbursement in many healthcare systems is not taking this into account. Further the reimbursement for certain procedures in countries is already now sometimes not even covering a part of the cost of the product (even if the product is low cost) departments therefore have to refuse to do certain diagnostic or therapeutic procedures in NM as they are loss making. Contrary to regular pharmaceutical APIs this production capacity could not be moved to low cost / Asian countries since they are radioactive and the infrastructure in these countries is not as advanced. This has already led to companies closing factories or leaving the business altogether. So far this loss of production capacity could be covered by the remaining companies ramping up, but the investments need to be covered by adequate reimbursement of procedures. Due to the small size and the complex supply chain of the NM industry in comparison to others the relative amount of investment that need to be made are much higher than for “regular” pharmaceutical industry.

Another problematic issue is the fact that most of the stable isotopes needed for radiopharmaceutical production still stem from Russia. So far these have not been sanctioned and although EU based companies have started programs to produce these essential starting materials, the situation is still fragile and uncertain if we can replicate all necessary APIs.

How is the industry dealing with potential radiopharmaceutical shortages?

Nuclear Medicine Europe represents many of the major pharmaceutical & Imaging equipment companies in the field of Nuclear Medicine in Europe. It's Security of Supply working group e.g. coordinates the schedules of the principal 6 reactors in order to ensure that there are no overlapping maintenance and fuel replacement schedules. If anything unforeseen occurs the Emergency Response Team meets to, when feasible, realign schedules to ensure capacity of production and limit disruptions.

Therefore Nuclear Medicine Europe is already since 1992 doing what the Critical Medicines Alliance is striving to achieve; ensuring a steady supply of medicines for European citizens.