

Gergely J  noki CEO, Medi-Radiopharma, Hungary



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Gergely J  noki CEO of Medi-Radiopharma shares his insights on the activities of the company, the trends in the radiopharmaceutical industry while highlighting regulatory trends, the importance of quality, the driving factors behind the company  s success and his long-term vision of for the company.

Can you introduce the field of radiopharmaceutical and the activities of Medi-Radiopharma?

Nuclear medicine can be separated into two big groups: diagnostics and therapy. In the field of diagnostics, specific radioisotopes are selected for their properties to allow specific devices to image tissues, organs or cells. This allows physicians to identify anomalies in the biological functions or tumour growths. Radiopharmaceuticals are increasingly in demand for therapy, in large driven by the theragnostic concept. Theragnostic molecules targets and kills cancer cells while sparing healthy tissue. Thanks to breakthroughs in neurocranial tumour and prostate tumour treatment, this has brought nuclear medicine into the spotlight. It has become such an important field, that Novartis invested EUR 6 billion (USD 6.7 billion) in nuclear medicine to expand their capabilities.

Medi-Radiopharma was established in 1997 by my father and is a Hungarian privately held company. It has been operating over two decades and its success story reflects his passion and commitment. Medi-Radiopharma operates in the field of nuclear medicine and provides 16 different

technetium cold kits which are used for diagnostic purposes to over 70 countries. 80 percent of all the radio imaging in the world is conducted with technetium, and our cold kits cater to this market. Our company's forte is to manufacture sterile lyophilized drug products with the highest quality possible while offering a broad portfolio. Our spectrum of product offering competes and complements the portfolio of GE Healthcare or Curium Pharma itself in Europe.

To whom does Medi-Radiopharma provide these products to?

The purpose of Medi-Radiopharma is to serve healthcare through our high-quality products, to improve patient outcomes. The company services anyone who is in need, which means we sell directly to hospitals—state-owned or private—, clinics, clinicians, big pharma companies and distributors.

How have the performance between this year for Medi-Radiopharma?

We grew more than 60 percent this year and the demand for our products has been booming. Over the years, Medi-Radiopharma has managed to steadily increase its turnover and size even through recessions. Part of this success is due to the organizational improvement in our manufacturing processes, and by transitioning from a small to a medium-sized company. Our business decisions are not driven by profits or higher turnover. Medi-Radiopharma's product quality is its competitive advantage, and that is never compromised for the sake of increased margins. Also, it has a customer-centric approach and together compiles the driving strategies of the company.

How does Medi-Radiopharma assure to provide consistent quality to its customers?

We improve technical readiness in terms of analytical equipment, invest in training for our young and talented employees, and we have 24 years of know-how in the field and support the clinical practice by providing Q.C kits also. Since Medi-Radiopharma was founded, that ownership of quality comes first. Quality assurance has top priority over any other department but collaborates well with the others to deliver what we have in mind. They, of course, enjoy the full support of the top management.

How competitive is the radiopharmaceutical market in Hungary and the CEE region?

The Hungarian market is saturated, and it would be of benefit to see some investments made in hospitals to re-stimulate these health economies. Currently, GPs and specialized practitioners are overburdened with administrative tasks or suffer from staff shortages, which makes maintaining the level of treatments and diagnosis in deteriorating conditions extremely difficult.

Furthermore, radiology and nuclear medicine departments are clashing, as they are overbalanced in favour of radiology. These two areas are complementary as radiology is essential for discerning the morphology of organs and tissues, while nuclear medicine reveals whether it is functioning properly. However, in Hungary, the trend that we are seeing is nuclear medicine departments in hospitals are closing only to be replaced with radiological ones. This is not sustainable, and it is harmful to the healthcare ecosystem in the long run especially because there are therapeutic radiopharmaceuticals

that can only be used by nuclear medicine.

How does Europe compare to CEE in terms of performance and radiopharmaceutical regulations?

Hungary represents less than 5 per cent of annual revenue and is a small yet especially important market for Medi-Radiopharma. In developed countries, the market is booming, and regulatory policies have clearly defined the rights of the patients as well as the scope of radiopharmaceutical applications. This has allowed institutions like Bad Berka in Germany, under the auspice of Prof. Richard Baum to drive the field of theragnostics.

However, this is not the case in the CEE. Patients in that region will have to travel to Switzerland or Germany to have treatments at high cost that can save their lives.

What are some of the challenges that smaller companies like Medi-Radiopharma face in the market?

Besides our ongoing R&D we prepare to develop new diagnostic and therapeutic radiopharmaceuticals. WE ARE INVESTING IN a new production facility to increase our capacity as well as bring us one step closer to enter the US market.

What are the most important markets for Medi-Radiopharma and the next steps in the strategy?

The company distributing to over 70 countries, of which Africa, Australia, Asia, Europe, South America, India, Russia, and the Middle East are part of it. We cater to a wide range of products, and they vary depending on shifting demands. Nevertheless, the main source of revenue comes from developed countries as there is demand, pricing opportunities are better, but more importantly, the regulatory framework is supportive of such therapies.

Medi-Radiopharma holds a valid Manufacturer's Authorization, certificate of GMP Compliance, Wholesale Distribution Authorization, Certificate of GDP Compliance, Good Laboratory Practice (GLP) Certificate, wholesale distribution license for radiopharmaceuticals – besides the animal testing, isotopes licence, ISO Certificate and relevant authorization for the manufacture.

In addition to the above-mentioned existing licenses, the goal would be to receive US FDA and the Japanese MHW approval, solidifying quality deliverance of our products. However, Medi-Radiopharma will achieve this by growing organically and finalize the new facility to meet these new milestones.

In your 11 years as CEO, what has been one of your proudest moment?

My team and my father have been my biggest source of pride. Without him establishing the foundations it would not have allowed me to hire these exceptional people. It not just because they are passionate and talented, but they are ambitious.

What your long-term visions for the company in the next five years?

Additionally, for diagnostic radiopharmaceuticals we want to provide products for therapies because we do not want to have any patients who miss a treatment because of a lack of supply.

What is a business lesson that you have learned while working for Medi-Radiopharma?

It is remarkable how surprisingly positive employees react when you give them unconditional trust and how they reward you with exceptional results.

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