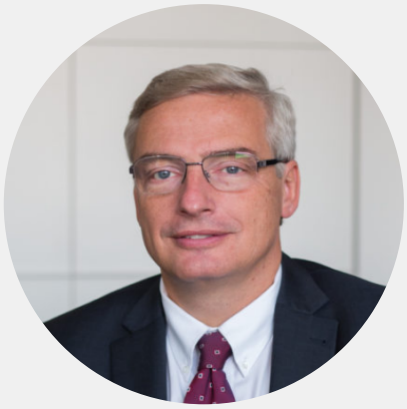
Mátyás Szentiványi – Director General, National Institute of Pharmacy and Nutrition (OGYEI), Hungary



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Dr Mátyás Szentiványi, Director General of

the National Institute of Pharmacy and Nutrition (OGYEI), introduces the administrative authority and specifies his strategy to be an increasingly collaborative and communicative body of Hungary's health regulation framework. Dr Szentiványi also goes on to comment on the current key challenges facing the sector, such as drug shortages and a new EU regulation related to the serialization of drugs.

Please proceed by introducing the National Institute of Pharmacy and Nutrition (OGYEI) and its responsibilities.

OGYEI is one of the most active and competent authorities in Central Eastern Europe (CEE). Having a very comprehensive role, it acts as the authority for conducting technological appraisals, approving medical products, reviewing clinical trial submissions, inspecting the entire spectrum of production activities such as GMP, and more. In addition to our pharmaceutical activities, we also have a nutrition arm of our operations in which we act as an advisor in the area of food and dietary

supplements.

Outside of Hungary, OGYEI takes part in a broad scope of international activities and we participate in all the committees of the EMA. By taking such a hands-on role, we are able to implement policies that are set at the European level as quickly as possible in Hungary. We are also actively taking part in international activities such as drug approvals, and also act as a reference country. In this context, we are working to solidify Hungary’s status as a recognized and strategic member state of the EU.

Furthermore, OGYEI provides scientific consulting services to healthcare and life sciences stakeholders. This is a crucial task for OGYEI, because it gives us the chance to get involved with the ecosystem and create a dialogue with other government bodies as well as the industry.

What do you consider to be the key priorities of OGYEI since being appointed as Director General last October?

Having had a longstanding career in the pharmaceutical industry, I aim to bring a new mindset to OGYEI. For example, as we are a government organization, decision-making can sometimes be slow and bureaucratic. It has been my goal to streamline this process in areas where we have sufficient expertise, and there is room for more successful deadlines. Furthermore, I have aspired to create a clear regulatory framework for activities such as drug promotion, which are often interpreted differently by government, industry, doctors, etc.

Overall, I want OGYEI to be a communicative and supportive organization within Hungary’s healthcare system. For example, keeping the industry informed of the policy changes and working together to decide on the appropriate deadlines in order to meet these goals. In the end, the goal of the OGYEI is to ensure that all the drugs and medical products crucial for Hungarian patients can be accessed from the market. While our policy decisions are made internally, and based on good scientific data, we are open to discussion when it comes to implementation.

How do you assess the current status of licensing and registration of products in Hungary compared to other EU countries?

We have best practices in Hungary when it comes to our authorization processes, and there is a very strong network of communication within the organization. Last year, OGYEI was audited by the

Benchmarking of European Medicines Agency (BEMA), who recognized our internal process as a best practice. OGYEI's approval process is based on facts and having a thorough understanding of the technology across different areas of the organization.

How does OGYEI manage the evaluation of different products such as pharmaceuticals versus medical devices, considering the institution just took on this area as well in 2017?

Having internal expertise is essential. This goes beyond the assessment of pharmaceuticals and medical devices, but is also crucial for the advisory role that OGYEI plays in Hungary's health administration ecosystem. For example, next year we will be implementing an initiative against MDR, in which we will work with the industry to raise awareness for this critical issue.

What would you highlight as the main strength of the Hungarian life sciences ecosystem?

By looking at the success stories of Gedeon Richter and Egis, it is clear that Hungary has a strong pharma tradition with advanced capabilities and skilled experts in the area. Furthermore, Hungary has a robust academic network with high research output. From both the industry and the academic side, these organizations have a long history and collaborate closely and very regularly. As a competent authority, OGYEI is in a good position to find experts and key opinion leaders in all major fields of life science. This is an important asset that allows us to partake in international healthcare discussions.

This February the prescription pharmaceutical packaging identification system was put into action across the EU. How ready were Hungarian manufacturers to embrace this new regulatory requirement?

When the regulation was first introduced, there was heavy resistance from the industry, not only in Hungary but also across Europe. However, resisting such changes almost always leads to delays in adoption. Therefore, we made sure we were prepared in Hungary before February, and even established our own HUMVO (Hungarian Pharmaceutical Identification Non-profit Limited Liability Company) to facilitate the process.

Although we started on February 9th, of the rest of Europe is still in the system's stabilization process. Our main priority is brainstorming with key participants in the industry to come up with solutions as how to overcome this transition as fluidly as possible. In fact, among the EU member states, Hungary is in a great position, being the second country after the Czech Republic in having the most successful pharmaceutical transactions in correlation to the population – if 100 percent is the hypothetical goal, we are currently at 120 percent. However, there are still types of pharmacies that are resisting cooperation. In partnership with HUMVO, we are identifying these pharmacies, and will eventually enact sanctions against those that are not using the system correctly.

To what extent is the falsification of medicine an issue in Hungary?

Fortunately, legal drug supply chain facilitation has never been an issue. When patients buy drugs from an accredited pharmacy or their website, they can be sure the product is certified, which is a major accomplishment of Hungary's well-organized healthcare system. Regardless of past falsification occurrences, we must partake in the European drug identification system, otherwise Hungary could become the weak link in the chain, and falsification could in fact become a problem here.

What steps is OGYEI taking in cooperation with the industry to combat the challenge of drug shortages in Hungary?

As the drug authority in Hungary, if there is a drug shortage, the market authorization holder must inform OGYEI about the issue, then we organize the resupplying or substitution of the product. However, vitamin K was an example that could not be substituted. In these cases, OGYEI can either give individual import licenses to applicants or enact a contingency to allow wholesalers to bring in a greater amount of the drug at a time. In a worst-case scenario, we can also demand the manufacturer to temporarily license the drug to another company here in Hungary to support further production.

As an authoritative body and supporting partner of the industry, OGYEI must receive the news of drug shortages in advance to act on this issue even earlier. Being able to apply preventative measures to avoid a drug shortage before it actually occurs is our goal rather than having to quickly react to a shortage once it has already happened.

What is the scope of OGYEI's recently forged collaboration with the Hungarian Chamber of Pharmacists?

Before my arrival in OGYEI, the relationship with the chamber was not strong enough. Now our goal is to act as a supporter of pharmacists and while we are aiming to reduce the number of inspections per pharmacy, this year we have been able to inspect Hungary's approximately 3,000 pharmacies. This allowed our team to better understand the situation of pharmacists, their needs, and also to share our knowledge with them.

OGYEI organizes training sessions for pharmacists twice a year, and we are now trying to make these sessions more accessible by conducting them outside of Budapest as well. In addition, we are partnered with the Chamber to establish adherence programs that help ensure patients are well educated on how to take their medication properly.

What are the significant collaboration opportunities with the pharmaceutical industry?

The biggest opportunity is the scientific advisory and consulting that OGYEI can offer to the industry. Additionally, we offer open consultation workshops which we have already done on biosimilars, patient support programs and drug promotion. These are important activities not only to make sure that all stakeholders are seeing issues at the same level, but also in supporting SMEs. We understand that these organizations may be under budget restraints, so we take the necessary steps to offer flat rates for these services to companies that are small in size, or just getting started.

Another key area for collaboration between OGYEI and the industry is in clinical trials – a very important contributor to the Hungarian economy. Clinical research activities generate between HUF 70 and 100 billion (USD 240 – 340 million) each year. Thanks to Hungary's centralized healthcare, companies looking to conduct clinical trials here can find the right number of patients with good quality sites all while being supported by OGYEI.

What expectations do you have for Hungarian health in the long-term future?

It is very important in the future that life expectancy in Hungary improves. With women it is above 80 years of age, while with men it is still closer to 70. To continue raising this figure would be an important KPI in measuring the effectiveness of the Hungarian healthcare system. Furthermore, we

must find more strategic ways to combine and manage the public health expenditure of the government with the out-of-pocket expenditure of citizens. Hungary has a good health infrastructure and skilled professionals, so our goal is to continue improving to create an even stronger healthcare environment.

Any final message you would like to deliver on behalf of OGYEI to Hungary's healthcare sector?

Hungary is a well-developing country as we can see by the growing GDP in recent years. While there is a mixed view amongst Hungarians about healthcare in the country, all stakeholders have been making conscious efforts for enhancement, and as a Hungarian, I believe we can really trust our healthcare sector. There are many opportunities to work together among all stakeholders to further educate citizens about health, which we should be conscious to take advantage of.

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