

# Attila Lukács - General Manager, CSL Behring Hungary, Romania & Bulgaria

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*Attila Lukács, general manager Hungary, Romania, Bulgaria for CSL Behring outlines emergent trends in the Hungarian plasma medication market, how the affiliate has succeeded in becoming a partner to patient associations in Hungary, and his strategic priorities for the future.*

**In 2017 you took on new responsibility, managing Hungary, Romania, Bulgaria and for 1.5 years Slovenia. How has this addition to your responsibilities been so far?**

Taking on these countries has significantly changed our responsibility here in Budapest and I am very thankful for the opportunity to better understand these markets. I have been involved in these markets in the past but not to the extent to which I am working now. In these countries, we operate through local distributors who are responsible for representing CSL Behring. We needed to build up quickly our relationship with local stakeholders, as this period was quite turbulent. It was nice to see that payers (MoH, NHIF) were open to different negotiations with representatives of our industries in order to solve critical shortages of some of the product range.

**When we last met in 2016, you were four years into the establishment of CSL Behring in the market and doing well. What have been the major developments for the affiliate**

## **since then?**

Within the past three years, we have been quite successful and have been able to significantly develop our portfolio in Hungary and launch new products. Although CSL Behring entered into the Hungarian market quite late, only eight years ago, compared with competitors who entered 15 or more years earlier, we were able to establish a strong market position, regardless. Within this short period, we have become the market leader within our segments of plasma-derived medicines and recombinant biotherapeutics. These segments may be relatively small, but there are between four and seven different players in the areas and we still hold about 32 percent of market share. CSL Behring provides the widest product portfolio for Hungarian patients, which offers us significant opportunities and flexibility. We also needed to be flexible to adapt to the quickly changing market environment. What I am most proud of is how we have been able to build a relationship with the entire ecosystem, including patients, associations, healthcare providers, and even government stakeholders and payers.

## **What would you highlight as the main trends shaping the Hungarian plasma-products market?**

The first trend is that the market landscape has become even more competitive than it was eight years ago. When we first entered in 2012, CSL Behring faced harsh competition. As we are the global leader in our area, many of the players already in the market felt very threatened by our presence. With the market environment changing and more tenders being implemented, the competition has become more serious than ever.

Next, the consumption and market access of different products and therapeutic areas are increasing nicely. As an example, when we first entered Hungary, the overall access to immunoglobins for the most impacted patient pool with primary immune deficiencies was not the best. However, with CSL Behring's significant contribution to facing this challenge, the industry was able to resolve the issue and now all primary immune-deficient patients have these products reimbursed and treated without real limitation.

There are other nice examples for this as well, such as in Hemophilia, where all patients are treated with factor concentrate. NHIF is also open to funding new mode of action therapies.

## **Where do you stand today in terms of expanding the portfolio of CSL Behring in Hungary?**

We could successfully introduce a new treatment concept for patients in perioperative bleeding management, which occurs during major bleeding. It happens in many cases, such as in: trauma, following serious injury; obstetrics settings during childbirth; liver transplantation; cardio surgery; and gastroenterological bleeding. CSL Behring's mission is to support the implementation of this program and, while we are not present in some areas of this program, such as anaemia or iron deficiency supplementation, we are working with all relevant stakeholders and medical societies to ensure success. In line with new EU guidelines, instead of fresh, frozen plasma, rather factor concentrates (fibrinogen or 4 factor content products) are already widely used. Based on this new concept, mortality and morbidity can be significantly decreased; less hospitalization is needed, especially days in intensive care units decrease; and thus overall treatment cost can be reduced.

Hungary is a country in which the demand for blood transfusions is about equivalent to the domestic supply – we are on the edge and we do not have reserves, especially not of red blood cell and platelet transfusions. However, by reducing the use of transfusion needs, with the implementation of perioperative bleeding management, hospitals will be able to better manage its demand, which is in the interests of all healthcare professionals, stakeholders, authorities and patients.

## **CSL Behring's global performance was driven by the company's recently launched products IDELVION for the treatment of Hemophilia B and HAEGARDA (Berinert sc. in Europe) for Hereditary Angioedema (HAE). Have these products been introduced in the Hungarian market?**

Neither of these two products has been introduced in the Hungarian market yet. In fact, HAEGARDA (Berinert sc.) has still not been launched in a majority of European markets, but we hope to accomplish this soon. However, we do have one globally recognized KOL from Hungary in this therapeutic area and she has already reached out to us acknowledging this innovative therapy and has begun analyzing how it could potentially be introduced in the country.

IDELVION is a long-acting recombinant Factor IX therapy for which we are currently in negotiation with the national health insurance fund for how we can improve access to the product. At the moment, the accessibility of IDELVION is about to recognize the added value of the product provides to patients which really significant compared to standard therapies.

## **What is your assessment of Hungary's current market access conditions?**

Across this region, especially in Hungary, reimbursement is crucial to patient access to our treatments. Unfortunately, in the overall medicines space, Hungary is far behind even our other CEE peers. As I manage Bulgaria, Romania, and even Slovenia for a time, I have a benchmark reference for what access conditions are like in the other markets. In these countries, there are areas in which the reimbursement process is faster and more transparent. The lengthy and unpredictable reimbursement process is one of the most significant challenges in the Hungarian market.

Additionally, Hungary has one of the strictest price-referencing systems in place. This then plays into how products are analyzed for cost-effectiveness in the country. The evaluation system is not adequately effective because some innovative products cannot be benchmarked by the existing standard of care, which has extremely low costs, such as steroids or antibiotics. This limits the growth opportunities not only for CSL Behring, but all of the pharma industry here in Hungary. I would even go so far as to say that because of this evaluation criteria, certain innovative brands and products will never be launched in Hungary and reach the patients here.

## **To what extent is the regulatory and reimbursement pathway in Hungary adapted to the characteristics of plasma products?**

Recently, more and more products have faced supply shortages in Europe and Hungary, too. This is not only relevant to our segments, but also in many others in the pharma market, in which CSL Behring is not present. In our case specifically, the biggest supply limitation exists for immunoglobulin products. We have though, experienced a positive attitude from stakeholders, payers, as we worked together with local authorities to help resolve the solution quickly.

The primary growth driver for CSL Behring globally is immunoglobulins, as a result of the rapidly increasing medical demand worldwide. As immunoglobins are also produced from plasma, it takes 7-9 months to manufacture these products and the overall industry cannot meet the need, with its current production capacity. The global market, therefore, has had to manage supply limitations that had an impact here in Europe and the CEE region, too. While Romania struggled for months with complete shortages, the Hungarian authorities recognized the problem and involved all stakeholders from industry to patient groups, to create a solution. CSL Behring took the lead in first

making sure that the authorities and patient associations understood the global trends of the situation, and on the other hand, compensated for the supply limitations of some local competitors, to ensure the continuation of patient care with immunoglobins. I would also like to point out that the authorities took appropriate steps to recognize the value of this therapy, to ensure that Hungary could avoid shortages.

While there is still much room for improvement when it comes to access in Hungary, this is just one of several examples that highlight the gradual developments being made in the country to improve conditions.

**Given your close relationship across the health value chain, what is the positioning you are aiming to establish for the affiliate?**

We position ourselves as the most relevant and reliable supplier of plasma-derived products in Hungary. Tackling the areas of unmet need with a patient-centric focus is essential for CSL Behring. Within our segment, we see different levels of development in various disease areas. For example, haemophilia patients have the best-ranked access to therapies in the world, which boils down to how powerful the patient associations are and how committed the scientific community is. However, access to immunoglobins or perioperative bleeding management for acquired bleeding patients from trauma, for example, is still underdeveloped. Even though there may not be traditional patient groups in these instances, CSL Behring is dedicated to making sure that these patients also are able to have access to such life-saving treatments. CSL Behring's motto is "Driven by our promise", which refers to the promise of being the most reliable supplier, ensuring the utmost quality, and delivering products to those in need, that is, our patients.

**Hungary is now home to three of CSL Behring's European plasma collection centres. What is the capacity of these centres in collecting the plasma necessary to develop CSL Behring's life-saving therapies?**

A majority of the plasma supply globally is sourced from the US - about 60 percent. In Europe, around 40 percent of products in this segment are manufactured with plasma from the US. Therefore, Europe is not self-sufficient in its supply of plasma. That is why it is so important that five years ago, CSL Plasma decided to open its first donation centres here in Hungary. At the industry level, we are collecting a huge quantity of plasma. However, the capacity of the centres is

still not at the output at which it could be, due to conservative regulations at European level, which restricts the number of donations, on top of Hungary's own restrictive policies. Therefore, we are working closely with the government to express the importance of facilitating the ease of donation.

We established a local entity of CSL Plasma five years ago, and two years later split it into two separate operations. Although we are working separately, I can say that CSL Plasma is the most ethical organization, when it comes to reaching out and raising awareness amongst and for donors.

**Now that you have been leading the affiliate for nearly eight years, are you satisfied with where CSL Behring Hungary stands today?**

Certainly! We are very proud of what we have accomplished in this time. I can say I am pleased with the relationships we have built with patient associations, healthcare professionals, and even the government authorities here in Hungary. There are still many opportunities to further increase access for patients and to expand our footprint into new areas, such as immunology, where patients need immunoglobulins in neurologic or haematological indications, for example.

**Looking forward, what are your current priorities for CSL Behring in Hungary over the next several years?**

We are aiming to launch new products in Hungary in the areas of haemophilia and specialty care while improving access to new indications from our current portfolio. Additionally, I would like to further evaluate how Hungary can benefit from increased capabilities of collecting local plasma.

**You have been successful in establishing an affiliate in Hungary from the ground up and developing into a trusted health partner. What advice can you offer to your peers looking to emulate this process?**

CSL Behring Hungary has exhibited a strong example that cooperation with health stakeholders, including patient associations, is crucial. Whether talking about market access, patient communities, or products, we always keep an open line of dialogue. Understanding the needs of patients should be the number one priority of any pharma company. In fact, CSL Behring recently launched a CSR initiative, executed on a regional scale, where we dedicated one full day for all countries across CEE to participate in unique activities to benefit the patient community. In

Hungary, the entire CSL Behring team decorated the treatment rooms of the country's largest pediatric hospital, Pál Heim Children's Hospital, where patients with serious diseases are treated. We also donated equipment, such as anti-decubitus beds and elliptical trainers, to aid in patient recovery. Corporate Social Responsibility is very important and valuable for our company, too - we got a little out of our daily routine, and we felt so good to do good to those little patients with such serious conditions.

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