Jiří Žák – Chairman, FARMAK, Czech Republic

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In 1996, Jiří Žák, chairman & current CEO of FARMAK, took over the state-owned producer of vitamins FARMAKON where he previously worked for 30 years and turned it into a flourishing private company focused on the research, development, and production of active pharmaceutical ingredients (APIs), intermediates, and specialized chemicals. Žák shares the early success of FARMAK in the US and his internationalization strategy through its recent entry on the Brazilian and Japanese markets, as well as how the company has adapted to the evolution of the API industry and continued to remain sharp against fierce competition globally.

Jiří, could you start by introducing the footprint and operations of FARMAK?

FARMAK is rooted in the history of the Czech Republic. Our manufacturing site was originally built in 1934 as a chemical factory producing solvents and basic chemicals. During World War II, it was given to Theodor Morell, the doctor of Adolf Hitler, to produce drugs for the German army. After the war, the company started the mass production of pharmaceutical APIs based on German know-how. In the 1950s, the site was then repurposed as a state-owned manufacturer of vitamins and generic drugs called FARMAKON.

I started working at FARMAKON almost 60 years ago. After the Velvet Revolution, I borrowed half a billion Czech crowns to take over the company and renamed it FARMAK in 1996. However, it was clear that we could not remain competitive in the global market solely in the production of vitamins

C and B2 as our volumes were too small compared to our competitors. As a result, in 1996, we started collaborating with a Swiss company, owned by a big multinational corporation and began producing new generics, some of which we still produce to this day. Thanks to this collaboration, we were able to enter the US market rapidly, which was my dream. As the first entrant on the US market, we benefited from this tremendous advantage, supplying a huge number of products at a relatively high price, which boosted our revenues. During the first two years, we grabbed 80 percent market share from the originator product. Thanks to this success, we were able to pay back the loan for privatization. Of course, since then, competitors have entered the market, eating away at our market share and pushing down the price of the drug.

How have you adapted to increased competition in the API industry, especially from low-cost countries like India and China?

Increased competition from India means we need to produce more at a lower price point. However, in the Czech Republic, personnel costs increase by ten percent every year while the productivity of labour stays the same. Moreover, the cost of raw materials and energy are increasing as well. As a result, we are under pressure to develop new products to generate better income which means investing more in research. We invest as much as we can in R&D, about CZK 30 million (EUR 1.2 million) per year.

Simultaneously, timelines for the development of new generics has changed dramatically. In the past, we started developing new APIs two or three years before patent expiration. Nowadays, five years is already too late. Today, companies look for products which will expire in ten years. In some cases, these products are still in the clinical stage. Indian and Chinese companies are especially eager to synthesize every molecule.

As our R&D and manufacturing capacity is limited, it is crucial to study the market to identify niche products which will lose patent protection in the next five to ten years. The US market serves as a good indicator of the patent situation in other developed markets. If five to ten companies are already registered in the US, we are already too late. Our target is to start developing two or three new products every year. Timing of the scale-up phase is also decisive to minimize risk because it is incredibly capital-intensive. In order to be able to offer products, we must prepare three validated batches for sampling to meet the minimal technical requirements five years before patent expiration, which requires investing several million Czech Crowns. While the quality of our product is guaranteed for five years, scaling-up three years before patent expiration would not

make sense because no company would accept a material which has been sitting in storage for that long.

If a company comes to us with a process to produce a certain product on a contract manufacturing basis, the situation is easier, although the volume must be reasonable. Every week, we receive at least one request for contract manufacturing, and every year we introduce at least one new product, mainly final APIs, to our contract manufacturing portfolio.

However, most of our activity is in developing our own product portfolio before we know who the clients will be, which of course means higher risk. The advantage is having our own labs.

Since your initial success in the US market, how have you continued to grow your international reach?

In the last five years, thanks to the hard work of our commercial team, we have built a strong foothold in Brazil and Japan, which helped boost revenue by 15 percent to USD 26 million in 2019. The Japanese and Brazilian markets have one thing in common: both have high regulatory requirements. To put things into perspective, in the US, introducing a new product takes approximately two years, while in Brazil and Japan, it takes usually four years from submission to approval from Anvisa or the PMDA respectively. As a result, many companies, even European ones, do not try to enter these markets. In order to succeed, we chose a strong product with excellent quality to be able to pass all the requirements. Moreover, we knew that none of our competitors had the intention to introduce this product there.

In Brazil, it took us four years to receive approval for the molecule brimonidine, a medication used for open-angle glaucoma or ocular hypertension. Now that we have approval, we are growing rapidly. The first commercial supply began in 2015 and since then we have added many clients to our portfolio, which is very exciting! It was a similar story in Japan. We started supplying brimonidine to one of the largest ophthalmology companies there. Today, out of the top ten ophthalmology companies in Japan, nine of them are using our material.

While competition from India has increased, Indian manufacturers of APIs and final dosage forms are still plagued by quality issues with 19 warning letters issued by the FDA in 2019. How have you capitalized on this situation?

Manufacturers of final dosage forms must declare that the material used in their formulation comes from an FDA-approved supplier. However, Indian API manufacturers have not adapted their quality control capabilities to the rapidly strengthening regulatory requirements. As a result, one of the largest Indian manufacturers of final dosage forms came to us to supply tizanidine hydrochloride, a short-acting muscle relaxer that is used to treat muscle spasticity due to spinal cord injury or multiple sclerosis, even though they have the ability to manufacture the API. One of our main strengths is that we have been FDA-approved since our first inspection in 1999. Since then, we have been inspected every two or three years, and have never received a warning letter.

Lately, you have been trying to enter China but the market poses challenges to a newcomer such as intellectual property issues and registration. How do you plan to overcome these challenges?

We are approaching the Chinese market very carefully as we have encountered issues in the past. We were approached by companies offering to help us with the registration process but have not delivered on their promises. We need to find a reliable partner, preferably one that is not only active on the Chinese market, and with Western staff for smoother communication.

Moreover, it seems like the structure of the generics and API manufacturing industry will be dramatically reshaped in the upcoming years. As there is overcapacity, Chinese authorities want to close down half of the factories there. In addition, it looks like the trade war between China and the US is making it harder for Chinese APIs and generic drug manufacturers to export to the US. The FDA is reducing the supply by issuing warning letters to Chinese manufacturers, and Trump has restricted the import of APIs from China and India for government requirements like the army.

What do you want potential customers to think when they hear the name FARMAK?

Our strategy is very simple: position FARMAK as a reliable partner supplying products that meet or exceed customers’ requirements. In the case of Brazil and Japan, we received experts from these two countries to train our regulatory team on how to create the necessary documentation, which was incredibly helpful. Beyond simply fulfilling requirements, the key is also predicting their evolution, an area where we are very strong.

Being a reliable partner also means doing business honestly and transparently. When I was younger, a simple handshake was enough to seal a deal, and promises were kept. Nowadays, you

need to sign ten pages of supply agreements, but it does not guarantee the promises will be honoured. I try to instil this culture of honesty and trust to my teams. Our word is our bond, and the customer is king.

Finally, what legacy do you want to leave behind?

In the last decade, we have invested about CZK one billion (EUR 39.6 million) of our own money in the business. My goal is to continue reinvesting our profits in order to keep growing and leave behind a thriving, debt-free and sound company for the next generation.

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