Interview: Wolfgang Schnitzel – General Manager; Karl-Heinz Hofbauer – Site Lead Vienna, Managing Director (Technical Operations), Shire Austria



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11.10.2017

Tags: Austria, Shire, Pharma, Manufacturing, Rare Diseases, Baxalta, M&A

Dr. Wolfgang Schnitzel, general manager of Shire Austria, and Karl-Heinz Hofbauer, site lead Vienna and managing director for the Technical Operations business, discuss the huge impact of Shire's 32 billion USD acquisition of Baxalta that has grown the workforce from a few Shire employees in Austria to 3,500. Furthermore, they highlight the leading position Shire has in shaping the Austrian rare disease community and the company's important role front in displaying Austria's world-class production capabilities.

The big news for Shire globally is the 32 billion USD acquisition of Baxalta in 2016. How has this impacted the operations of Shire Austria?

Wolfgang Schnitzel (WS): Shire started as a very small company in Austria; therefore, the global move to merge with Baxalta (formerly part of Baxter), which had a huge footprint here, was a game changer for us and is extremely exciting. The companies fit perfectly together and it allows us continue on our pathway to becoming a comprehensive global biotech company in rare diseases.

From a few employees at Shire, to now being the second largest pharmaceutical employer in Austria, it has triggered a large change in processes and the way we interact with stakeholders. Myself, I am the head of the Austrian rare disease working group that is dedicated towards this

therapeutic area as we endeavour to shape the Austrian rare disease environment, focusing on topics such as raising awareness on rare diseases and ensuring access to medicine.

Karl-Heinz Hofbauer (KH): Prior to the acquisition, I was working at Baxalta, and have been part of this group for the last 20 years. The merger has opened up an amazing amount of opportunities for Austria, especially due to the fact the companies' portfolios complement each other so well in the rare disease field. From a manufacturing perspective, it provides us with the ability to grow our production portfolio and volume. Shire's global reach is of importance, as we produce products not just for Austria, but for around 100 nations worldwide, with 98 percent of our products being exported.

What is the importance of Shire Austria within the company's global operations

KH: Today at Shire Austria we have around 3,500 employees, a large portion of the company's 24,000 global workforce. Baxalta brought to the Shire community technical expertise, such as the ability to manufacture on a big scale. If you look from that side of things, our technical operations staff of 2900 makes up a huge chunk of the company's 15,000 worldwide; therefore, it is obvious as a location how important Austria's role is in global processes. In Vienna, we are one of the largest manufacturing points when you look at our portfolio, moving through the entire production chain from raw materials all through to the finished product.

One of the key steps for rare disease patients is identifying them within a healthcare community. What is Shire Austria doing to help aid this process?

WS: For rare disease patients, statistics show that the period of diagnosis is approximately five years, with around 40 percent of patients being misdiagnosed prior to being diagnosed correctly. Therefore, the identifying of patients is an area we want to lead the market. We are not only committed to providing patients with therapy, but also raising overall rare disease awareness and educating medical personnel. Furthermore, we provide diagnostic kits to ensure early diagnosis and we support the needs of patients during treatment.

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Rare disease drugs are innovative treatments. Do you believe the Austrian healthcare system rewards innovation?

WS: Drug prices are often a criticism. Though if you look at the overall amount being spent in Austria annually on drugs it is increasing, more or less, by three percent, which is normal for a developed healthcare market. We have a good balance to be able to afford investments in new

therapies that cost more, while allowing other companies to provide generics at a cheaper price. This creates a stable system that ensures the Austrian healthcare market has a sustainable future ahead.

Should rare diseases be classed differently to normal innovative products when gaining market access?

WS: This is not the most beneficial step as this will require a dedicated budget that makes the system even more complex. I believe it is important that stakeholders acknowledge and understand more about rare diseases and the special needs of our patients. Many individuals believe because the patient group is small, so R&D costs are less, though this is the contrary; therefore, we must educate the broader healthcare ecosystem on Shire's operations.

For example, Shire Austria are the only representative of the pharmaceutical industry that are part of the expert rare disease group set up by the Ministry of Health. This allows us to explain the special circumstances we encounter and what is entailed in rare disease R&D from the industry's point of view.

Does the fact healthcare is focusing more on personalised treatment assist your cause?

What makes Austria an attractive destination to conduct such large-scale production?

KH: Especially in the rare disease space having the perfect production location with the appropriate requirements is of paramount importance. The company has a manufacturing legacy in Austria of more than 60 years due to a number of key factors. Firstly, Austria has an abundance of highly qualified employees and this is essential to meet the company's high standards, while in the meantime being able to drive forward innovation and enable production efficiency.

Secondly, the perfect infrastructure. We are dealing with products that are of high value; therefore, we must ensure that external factors do not affect our operations. Austria is world-renowned to be a stable country, both economically and politically, allowing operations to always run smoothly. Furthermore, the country is an attractive destination for world-class talent, both domestically and internationally. This allows our workforce to mimic the diversity of Shire globally.

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It is important that the Shire Austria team works collectively and that overall costs are kept in check and efficient. This will ensure that Austria remains an attractive location for Shire's headquarters to continually invest.

Do you believe the governments incentive of a 14 percent R&D rebate as of January 2018, will attract other companies to bring large operations to Austria?

KH: This incentive to bring R&D will as a consequence lead to positives, such as attracting more companies and equally more international experts, although there is a lot of competition in the region. It is very important that we take another aspect and focus on working closely with the universities to ensure our education system is envied, and this will only result in a more attractive destination in the long-term.

As one of the leading production companies here we have a responsibility to contribute within the local associations and act as an example to highlight the benefits for pharmaceutical companies to conduct industrial production in Austria. We work together with stakeholders and organizations to portray Austria as a great place to be actively present.

Shire Austria has huge production capabilities and conducts R&D operations. What more can be done to lure the eyes of headquarters to continually invest in the affiliate?

KH: Manufacturing wise, we must continue to deliver on our commitments and be a reliable supplier of products, while conducting projects in a timely manner. Furthermore, our team must provide innovate production solutions to increase flexibility, speed to market and reduce costs. These are the keys to any ideal investment site, and in areas such as R&D projects, we must hit our objectives. If we do all this headquarters will continually look positively at Shire Austria.

WS: It is essential to dedicate a clear commitment at the governmental level to create a positive climate towards rare diseases. We endeavour to be the forefront of the national plan for rare diseases and also implement national centers of excellence. If Austria as a healthcare community shows commitment towards rare diseases, this will result in making us even more attractive from an investment point of view.

Where will we see Shire Austria in the next five years?

KH: As a manufacturing location, we have a clear plan. A big portion of our operations are in immunology and this sector is growing; therefore, there is a need to increase our fractionation production capacity. Furthermore, we have a plan to produce additional products in Austria, from the company’s existing portfolio that are manufactured at other sites, and equally from the global pipeline that is aided by the company’s large R&D investments.

WS: Shire has a very exciting pipeline, with around 30 rare disease products currently in the clinical phase and with positive results, we want to launch these treatments. The challenge is to

contribute in shaping the rare disease environment and strengthen the company as the global and Austria leader in this area. This in-turn will allow our patients to have quick access to our life-changing treatments.

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