Interview: Manuel Reiberg – President, Forum of the Research-Based Pharmaceutical Industry (FOPI), Austria



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Manuel Reiberg, president of the Forum of the Research-Based Pharmaceutical Industry in Austria (FOPI), which represents the 27 leading pharmaceutical innovators in Austria focused on pharmaceutical innovation, discusses the struggles facing drug innovation under the new reimbursement system, as well as the steps that must be taken to bolster the Austrian innovation sector and attract international companies to establish themselves firmly in Austria. He also gives an overview of the digital revolution and the path Austria must take to consider itself a world innovation hub.

As president, could you introduce the Forum of the Research-Based Pharmaceutical Industry in Austria (FOPI) to our international readers?

FOPI currently represents 27 companies in the Austrian market that are focused on research and development in the pharmaceutical sector. Clear membership criteria states that 90 percent of revenues must be generated through innovative products. FOPI focuses on contributing to the further development of the market environment to ensure that drugs can move effectively from research stage to retail. We are facilitating a crucial step in a drug development cycle, so that patients in Austria can receive innovative treatment as early as possible. The more attractive the R&D environment for companies, the more value we can bring to the Austrian healthcare system.

How does the government reward companies along this process from research to retail?

There are two separate essential streams at the government level: research and market access. First and foremost, at a research level the Ministry of economics has drawn up a life sciences strategy using tax and investment incentives that should promote companies bringing research into Austria. This is not just in pharmaceuticals, but equally in biotech, so all in all there is a solid foundation between science and the industry. Pharmaceutical companies are sponsoring studies and currently over 500 of them are being run in Austria. Overall there is a steady flow of financing into research.

On the other hand, there are substantial concerns with the operations and reforms that have been put in place just recently for the social insurance organisation, the body responsible for reimbursement of drugs in Austria. These reimbursement reforms have brought severe containment measures; for example, fixed price bands have been put in place for generics. Therefore, new drugs entering the market cannot be priced 30 percent more than the cheapest product. Also, different categories have been introduced for reimbursement list drugs depending on the innovative status of the product. Any drug is priced based on European average pricing, though the Austrian government does not take into account other countries rebate strategies and so the drug is then under-priced on the domestic marketplace.

In summary, these changes are causing companies to reconsider bringing innovative drugs to the market, with the real fear that Austria is considered a second or third wave country for product launches, which would result in Austrian patients having to wait longer for innovative lifesaving medicines.

How can such an advanced healthcare system take a step back in an area like reimbursement?

The overriding reason is Austrian healthcare costs rose from three billion EUR (3.42 billion USD) in 2014 to 3.5 billion EUR (four billion USD) in 2015, driven by worldwide trends relating mainly to high priced, but equally highly effective, and overall cost-effective hepatitis C treatments. The Austrian government forecasted that overall healthcare costs would increase again by ten percent, in-turn, creating fears that the healthcare system, mainly financed by social contributions paid by employers and employees, would suffer and become unsustainable.

Therefore, the Austrian government and pharmaceutical companies signed an agreement stating that if healthcare costs annually increase above three percent the companies would cover the difference. Despite this agreement, the government decided to introduce the aforementioned cost

containment measures.

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What makes these reforms very challenging is the statistically verified fact that Austrian pharmaceutical and medication spending is only 12 percent of the overall healthcare expenditure. There are a large number of other areas where the government could leverage significantly more savings for the overall system; such as, ambulances and hospitals which at present are extremely cost inefficient.

What reforms would you put in place?

We believe the challenge is the running of therapeutic options for patients out of hospitals which has pushed patients to the primary care and retail settings.

For example – hypothetically – Hepatitis C treatment that is 100 percent effective costs around 60 thousand EUR (68 thousand USD) – although – the hospital setting to save money in the short term would prefer to treat patients with a less effective cheaper 30 thousand EUR (34 thousand USD) option. This could result in further down the line the patient needing to repeatedly return to the hospital – or even worse – receive a liver transplant. If effective innovative treatments are utilized we will see long terms savings rather than hospitals just considering savings in the direct treatment of the condition.

Secondly, we must improve the primary health care system. Currently health clinics have inconstant, and frankly, not hours of operation. Therefore, many patients are more inclined to go to hospitals, overcrowding them for conditions easily treated by a local doctor and wasting hospital resources.

The overall problem is that there are two separate financing streams, intramural (hospital) and retail, leading to decreased transparency in understanding the allocation of funds. As a result, we generally have no idea where we can make savings because we do not know where money is being spent. Most of the time hospitals cost more to run than primary healthcare, although unfortunately, in Austria we have no way to judge this. Furthermore, specific sick funds are located in each of the nine individual regions of Austria. We believe this should be unified under one fund to streamline processes and cut administration costs.

Merck, one of your members, has recently invested in a large production site. What opportunities in the manufacturing sector does Austria offer?

Austria already contains a plentiful supply of pharmaceutical production, with companies already investing, such as Boehringer Ingelheim which spent 700 million EUR (800 million USD) on a new production and development center for biopharmaceuticals in Vienna. Production infrastructure is adequate – nevertheless – the real contentious issue is the high production costs in Austria, which is not the case in production hubs like Asia, and in particular India.

More than ever, companies are facing rising pressure from a pricing perceptive, especially in Austria with cost containment measures in place. This impacts a company's ability to cover costs associated with years of research and development. For example, if a company spends billions per year for ten years on a drug, when this product is launched they want to generate an adequate return on investment. This results in nations with more expensive production, like Austria, being ruled out of the production process.

Are drug registration processes a factor in elongating drug development?

We could reduce administrative hurdles in this area. Collaboration between regions in Austria need to be improved with a more centralized process, decreasing administrative factors as well as standardizing processes, which leads to a harmonious environment to foster innovative launches. Drug safety is the largest obstruction to registration – nevertheless – this is important from our standpoint as it shows a due diligence to only allow high quality drugs to be administered to Austrian patients.

A hot topic currently is the digitalization of the healthcare industry. Do you believe Austria has the infrastructure in place to take full advantage of this digital revolution?

We have already begun this process, being one of the first countries to launch e-cards, indicating the willingness to utilize upcoming technological opportunities – although – we must do a lot more. The largest obstacle the market faces in digitalization is the fear from patients of what is being done with the data by external providers, data confidentiality, which generally throughout the world is a concern as the information can be hacked and accessed via the internet. Pharmaceutical companies are ready to take on this challenge, but we must first change this conservative approach by evolving the public's perception on such a system.

Firstly, as a pharmaceutical community we must stimulate the government to incite change by providing them with showcase business examples. For example, currently in patients in Germany taking more than three medications have this information saved on a system, a simple but effective change we are still yet to make in Austria. Furthermore, we are still yet to put in place a medication application for smartphones that allows patients to track and time their drug intakes.

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This digital involvement will take on a larger role for the reimbursement system as we will be able to make evidence based changes by showing the therapeutic success of treatments and collation information precisely and rapidly – furthermore – understanding the healthcare sectors we must further invest in. Managing diseases in this way will allow us help with basic principles of health that we lack in Austria, such as prevention.

What preventative measures are currently in place?

Primary and secondary prevention is a topic we actively discuss with the government; although, it is a dilemma because the individuals focusing preventative measures will not necessarily see the results for themselves. Austria can do a lot more at a youth level by accessing children from an early age in kindergartens and school and monitoring them throughout their lives. There is a direct correlation with the level of education and health – therefore – we must continue to teach young Austrians the most appropriate way to look after themselves and we have discussed this approach at a broader level together with the government and reimbursement institutions.

Let’s now look at Austria at the European level. What is inhibiting Austria from being an innovation hub like Switzerland or Germany?

We must incentivize companies to invest in R&D – moreover – there needs to be an attractive research into retail environments where drug development is adequately valued. Overall Austria needs a patient centric approach where the government looks not at the drug from a cost aspect – but takes a step back – and looks at the effect on the entire society and system. For example, a drug taken at home orally means less time off work in hospitals compared to an IV application, and the patient is more satisfied. This is a simple change but a clear example.

Furthermore, the market prognosis on the amounts being spent on Austrian healthcare has been incredibly inaccurate –some years by as much as 100 million EUR (114 million USD). When forecasts are off by such a large amount the government attempts to put in place cost saving measure; but the problem lies in the money being saved and not being reinvested back into the healthcare system. To ensure more accurate predictions are made we must create a transparent system with clearly defined spending between health sectors, allowing a sustainable system to flourish and funds to be used efficiently.

FOPI, in collaboration with Quintiles IMS, is constructing a comprehensive study, based on 6000 individual forecasts and incorporating the new reimbursement reforms, that will accurately predict

the next five years of the pharmaceutical environment in Austria. This takes into account significant factors such as company pipelines of innovative treatments, drugs coming off patent and being considered generics and establishing which therapeutic areas will be more prominent in the upcoming years.

With this we now have an accurate plan which creates a stable environment for pharmaceutical companies to operate – in-turn – attracting a comfortable market for investors to enter the market and set their roots in Austria. The results of the study will be released in two months and we cannot wait!

Vienna has been touted as possible destination for European Medicine Agency (EMA). What makes Vienna an attractive destination for such an important organization?

We must ensure as a pharmaceutical industry that EMA can seamlessly transition to not halt any processes, such as drug registration. EMA staff are experts in the field and we must ensure they are retained to ensure we do not lose their valuable knowledge. We believe Vienna is a very attractive location that allows EMA employees to relocate without any hassles. Vienna has great international schools, high quality of living, is safe, has great public transport and infrastructure and has an abundance of available properties. Furthermore, geographically Austria is perfectly located between western and eastern Europe, ensuring processes may run even more efficiently than when the EMA was located in London.

Austria will benefit most from the EMA´s relocation in its endeavor to become a European innovation and pharmaceutical hub. The EMA would increase the chances of establishing company clusters in the fantastic city of Vienna and helping us display to the pharmaceutical world the abundance of exciting opportunities available in Austria.

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