Interview: Wolfgang Andiel – President, OeGV, Austria

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Dr. Wolfgang Andiel, president of t

he Austrian Association of Generic Medicines (OeGV, Österreichischer Generikaverband), which acts as a unified voice to represent generics companies in Austria, provides an in-depth analysis of the vicious cycle associated with establishing generics market share in Austria as well as the inconsistences of government regulations in this sector. He also gives insights into the strategies being employed to incite change and the how the potential of hosting the EMA will influence the Austrian healthcare ecosystem.

As the President at OeGV, could you please introduce the association to our international readers?

OeGV was established in the year 2000 and is the representative of over 90 percent of the generics companies in Austria. OeGV is designed to strengthen the overall environment of the Austrian generic pharmaceuticals industry at a time when we are facing stiff competition from Asia, mainly in antibiotics, and the subcontinent, namely India. This is a concern at present for all Austrian generics producers and is changing the overall health ecosystem across Austria. Our job at OeGV, and as an entire industry, is to make this information tangible for politicians, as the reimbursement authorities – amongst others – are under appreciative of the importance of the role that pharmaceutical production plays in Austria as a high innovation industry sector.

We equally saw a need to establish a biosimilar association to cover this ever-growing sector, and in April 2016 we founded ‘Biosimilarsverband Austria’, a branch of OeGV. We have been supported

in this initiative by many large bodies, most importantly by the European Medicines Agency (EMA), giving us clout throughout the market.

At present, in pharmaceutical manufacturing and innovation Austria contains world-leading and local companies such as Sandoz, Fresenius,GL Pharma and Genericon, which create indirect and direct employment opportunities. As an association, we recently conducted a study to analyse the direct and indirect impact of the EUR 3.1 billion (USD 3.53 billion) generics production industry and its overall added value in Austria with a domestic business of EUR 3.3 billion (USD 3.75 billion) in terms of cross sales; divided one-third through hospitals and the following two-thirds reimbursement related.

OeGV is a member of the Austrian Medicines Verification Organization (AMVO), allowing us to align with the national sectors of industry originators, wholesalers and pharmacists under one umbrella in implementing the Falsified Medicines Directive. Finally, we meet regularly with other pharma industry associations to discuss common areas of concern, allowing us to have a unified voice with the government. Thus far the impact has been significant as collectively we understand the importance of such a venture to individually benefit each sector.

You have been in the generics industry for many years as an employee of Sandoz; how would you describe the evolution of the Austrian generics market?

Firstly, generics currently stand at a 50 percent volume share in the patent free market, and – in general – Europe´s generics industry is driven by expired patents. Generics in the Austrian healthcare environment have a 19 percent share and this from a percentage perspective is one of the lowest in Europe. In Austria, we are achieving an industry increase of one percent point per year; showing that the entire market in Austria is extremely stable.

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The reimbursement scheme drives the generics market, and the last time this system was reformed was back in 2004. The purpose of the reimbursement authority is to lower the price of the originator; furthermore, rulings state that once a third generics product is launched on the market, all similar products must match that price. Reimbursement authorities understand they must allow generics to enter the market to drive prices down; though on the other hand it is a burden for them to deal with such a diverse product and molecule range; therefore, crucial issues have arisen which I will highlight later on.

Austria is a prescription-driven ecosystem, with physicians primarily deciding which products to prescribe. When generics first come into Austria they obtain a large market share, with medical professionals generally prescribing this first option. The first generic launched is the most expensive; although this product generates the greatest prescription share and subsequently released generics – although being cheaper in price – are unable to penetrate the market adequately. This strive to gain penetration in the market directly leads to radical price erosion. In summary; it is a first in, first served system.

This is a major concern we discuss at the association as there is no economic benefit to gain market share here, therefore many companies do not endeavour to establish themselves in Austria. Nevertheless, there are also clear local success stories based around building relationships with health insurance providers, resulting in a generics market share of 70 percent with a reasonable percentage of protected innovative products, therefore also acting as a catalyst for innovation.

To sum up, currently we have a very stable situation as the reimbursement regulations have not changed in 10 years. This system though has created a bit of a riddle: earlier released drugs cost more, but have a greater market share.

How is OeGV attempting to rectify these complicated circumstances?

As mentioned before, we act as an active voice between the association and health authorities, reimbursement authorities and government. There needs to be a clear focus in generic penetration to incite a sustainable long-term effect. Lengthy discussions of ours have been concerned with biosimilar regulation as biosimilar products entering the market at a higher price are being rejected, as the government classifies biosimilars and generics as equals. This results in these drugs not being part of the reimbursement program, leading directly to a decreased quality of access to medicines for Austrian patients.

Additionally, biosimilars, when they do launch as generics, are priced very closely to the originator, so when the prices are matched, it does not result in a significant price drop. Furthermore, this minimal change does not catch the eye of the physicians, therefore they do not prescribe the new product, and this vicious cycle of pricing and market share continues.

We need to make clear to the key decision leaders that it is of paramount importance to find a balance in the current system to ensure a long-term perspective is achievable while attracting biosimilar companies to the market. For example, if a biosimilar in Germany costs more than the original product in Austria; why should they launch in Austria? We must explain this mechanism to

the government or this conundrum will continue well into Austria's future.

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OeGV has changed public opinion, with 70 percent of Austrians being in favour of generics. Nevertheless, only 37 percent of prescribed drugs are generics, much lower than other mature European markets. What needs to be done to incite change?

Firstly, a shift needs to be stimulated in the mindset of physicians, the chief decision makers behind every prescription. We must provide them with clear analysis and statistics on the benefits of generics for a sustainable patient supply with modern medicines, and at present this is our main focus. We also now know that in countries where the physician chambers and health insurance companies are well connected, there is a higher percentage of generics in the market.

Moreover, we must interact with pharmacies to diversify their prescription approach. At present, pharmacies have a tight-knit interaction with prescribers, hence only drugs stocked in these pharmacies are being distributed. This is especially prevalent in rural communities, and we see this alignment as a link we must break to influence generics market share and ensure the best treatments are being administered to patients.

Will changing the Austrian government's mindset save Austria money?

Absolutely! We calculate savings of 70 to 80 million EUR (80 to 90 million USD) by one percent growing generics share annually and this number will only improve year on year as the generic market increases.

How do you plan to convince the remaining 30 percent of Austrians on the benefits of generics?

Firstly, prescribers need to be convinced! They are the voice to the patients. We are a small association with limited resources; saying that, we are currently focusing on stakeholder meetings to convey to sales teams of our members the same message of promoting generics. We are now striving, along with the Austrian Agency for Health and Food Safety (AGES) to have a more patient-centric approach and to directly influence the Austrian patient's mentality towards generic drugs. All in all, we must continue to establish campaigns and focus on lobbying exercises.

In April, this year a new piece of legislation updated the maximum price of generics entering the market; now products will have to be priced 65 percent less than the original product price, compared to 60 percent previously. How does this change

influence generics companies?

Thankfully, I was part of the industry negotiation team during these talks as these changes influence us all directly. Personally, I see the percentage difference as reasonable, and really it was a goodwill gesture to demonstrate our willingness to accomplish results in the interest of both parties, the industry's and the payers'.

We also successfully discussed a new biosimilar pricing regulation but, unfortunately, positive changes in this area are restricted until 2021 and really hurts our cause. The current regulation states further, that drugs using the same molecules can't be priced higher than 30 percent above the cheapest product. Companies and products might therefore be forced out of Austria as this pricing does not generate sufficient returns. This might jeopardise the patient's supply.

In terms of other regulations, the repeated calculation of European average pricing for innovative products results in the original product price decreasing over time, even before the product comes off patent. This is not the long-term vision Austria requires and heavily affects the company of the original drug and jeopardises early access of products into the Austrian healthcare ecosystem.

Despite all these regulations, really there was no need to make any drastic changes. Over the last years the Pharma Master Agreement has been put in place, a stability program initiated to render a contribution to the social health insurance institutions and to support the performance of the social health insurance institutions, in particular towards the patients. While industry's contribution in 2016 was EUR 125 million (USD 142 million) the Sick Fund forecasted a catastrophic EUR 94 million (USD 106 million) loss from February 2016 until the end of the year. In reality, it turned out this prognosis was overly pessimistic and, during this forecasted period, Austria finished EUR 113 million (USD 128 million) in the black!

The EMA is looking to relocate in the EU after the Brexit announcement in the UK. How would hosting the EMA affect the life sciences industry in Austria?

Directly, Austria will have a huge influx of jobs; up to 900 high quality positions will become available in Vienna and – above all – it is a huge opportunity for the Austrian healthcare industry. We would attract current EMA employees and experts, offer different avenues of education for their children – and most importantly – will catalyse the development of Austrian R&D, such as the Research Institute of Molecular Pathology (IMP) and the Cancer Research Site of Boehringer Ingelheim. Vienna is a great city that the Austrian people are extremely proud of, and we are excited to welcome the EMA with open arms.

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