# Interview with Jan Oliver Huber, General Secretary, Austrian Pharmaceutical Industry Association (PHARMIG)

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**Secretary of PHARMIG since 2004 and have witnessed the marketâ??s development over the past 8 years. What have been the most important changes since you started your tenure?**

When I started in 2004, a new bill just passed, causing a significant change in the reimbursement system. And when you change a system, the growth rate goes down, because stakeholder are suddenly more cautious and need to adapt to this new system. Consequently, in 2004, 2005, and 2006, the Austrian pharmaceutical market experienced a lower growth rate.

Like other European countries, the Austrian population Is ageing. The part of the population over 60 represented 1.8m people in 1995; in 2030, 2.7m people will be above 60. This simply means that year on year, on average an additional 30,000 to 40,000 people join this 60+ age group. Considering two thirds of all prescriptions paid by the reimbursement system are destined to the this age group, there is a natural, organic growth in Austria because of the demographics. But this growth has not been steady: in 2005, the market grew by 1.65% whereas it grew by 8.29% in 2007 and by 7.41% in 2008.

When new innovative drugs come to the market, they are not automatically available for the patient. In fact, 70% of the total drug market in Austria is the reimbursement market. Therefore if a company is not in the reimbursement market, this company is not a key player.

It is difficult to enter this system, as certain restrictions exist. First of all, the maximum price of a drug within the reimbursement system in Austria is the EU average price. If your product is already on the reimbursement list in other European markets, you have to inform the Minister of Health (MOH), after which a price commission gives you clearance.

Moreover, since the 2004 bill I mentioned is in place, there is a system of colors on drug boxes which define their chances to be reimbursed. Drugs in the green box can be prescribed in general at any time by physicians and will be fully reimbursed; those in the yellow box can only be prescribed under special conditions that meet tightly defined rules for reimbursement; while physicians prescribing drugs in the â??noâ?? box will find it extremely hard to get reimbursement. In the yellow boxes are mostly innovative drugs, i.e. often the more expensive ones. This box system represents a certain hurdle for the industry in the sense that when your product is received as a â??green boxâ?? product, then you need to give a price discount. Over the past years, 90% of the products coming into green boxes were generics.

Austriaâ??s reference price system for original molecules and generics is probably the most severe system in Europe for pharma companies. According to this system, three months after your original

molecule goes off patent and the first generic â?? which has to be 48% below the price of the originator â?? comes into the reimbursement system, you have to reduce the price of your originator by 30%. When the second generic enters the reimbursement list, this generic has to be 15% lower than the first one; the third generic needs to be 10% lower than the second one. After another three months, the originator has to be at the same price as the third wave of generics, which is priced at around 39.8% of the initial price.

**Naturally the intention of this system is to significantly reduce the price of the originator. The reimbursement system tends to recommend physicians to prescribe generics. Nevertheless, after the third generic comes in, the originator and the generic are at the same price: so what is the argument for the prescriber or for the patient behind the prescription of the generic?**

As far as I know, in no other European country do the originators have to lower their price to the same level as the generic.

**PHARMIG represents a total of 120 companies employing 10.000 people, and covers almost the entire pharmaceutical market in Austria. To what extent do these companies share the same interests in this sector, and how challenging is it for you as an association which prides itself to speak as one voice, to regroup all members under the same umbrella and deal with potential conflicting interests?**

There are conflicts. But in most of the cases or questions that are raised within our association, it appears that all companies â?? innovative and generics â?? often face the same challenges: regulation, product value, reputation and image. Even as far as the reimbursement process is concerned, all members wish to have fast access to the reimbursement market. Innovators want fair prices; generics too: the higher the price for the originator, the higher the price of the generic.

For 85% of the issues we deal with as an association, members share common challenges. When there are different opinions regarding a particular issue, the board gets to decide through a majority vote that will be PHARMIGâ??s position towards that issue.

**Over the past few years, the line between generic and innovator companies seems to be less and less relevant, due to the growing trend of innovators integrating generic products in their portfolio through acquisition. To what extent is this reflected in the recent evolution of the associationâ??s membership structure, strategy, and propositions?**

In fact, in 2004, the generics company Sandoz was already a member. Novartis was one of the first key players to implement the model of a research-based pharmaceutical company with a strong generic arm. Other pharma companies have replicated the Novartis-Sandoz model in the meantime. Beyond this, other companies like Teva have a back integration, and develop important research and development (R&D) activities.

Today, we are one industry. Only we, between ourselves as industry players, make the distinction between generics and innovative companies â?? or perhaps also governments, for economic reasons. For the outside world, the consumers, the patients, whether the drug is a generic or an originator, does not make any difference; itâ??s just a drug that should help them.

Biological products are coming up in the market, and bio-similar products are taking a significant stand in our industry. The biotech companies in Vienna and around are excellent and receive a great support from the government. But without the pharmaceutical industry, biotech companies cannot take products to the patients worldwide. Therefore there is a natural common interest. Some traditional pharmaceutical companies already have their share in biotech companies because if you believe in the proposal and product of a biotech company, you will end up with a very strong

portfolio. Roche, for instance, acquired Genentech years ago (1990), and many of their new drugs brought to the market in the last decade came from Genentech.

**In most of the markets Focus Reports has been to, there are a minimum two or three associations, sometimes four or five, representing members with different interests and not necessarily aligned with one another in their strategy, a situation where governments find great satisfaction. In Austria, would you say your coverage gives you particular influence on government policies?**

The principle of â??one voiceâ?? was our first statement and has always been our main policy. In Austria there is also a generics association as well as an R&D association, and even though they are smaller in structure and size, their presence is beneficial to PHARMIG because we share similar issues. In principle, what is important is that we set the scene as PHARMIG, by making clear statements about our midterm and long term goals as well as our vision of a united industry.

When you want to be heard in the Parliament, government, or by other players in the healthcare system, it is not enough to say: â??we represent 95% of the marketâ??. You need to convince through know-how, service, transparency, lobbying, and by being a tough but fair negotiating partner.

**How would you rate the relationship between industry and government in Austria?**

The Minister always finds time for us; this is not the case in every country. Of course, they cannot meet all our expectations, as political decisions are always a compromise. But although from a political standpoint, we may have diverse views on certain issues, we always find an open door in the government. The communication with the health care Minister, and also with the other ministers, is excellent.

**Most European countries are facing cost containment policies arising from governments, and prices get squeezed. What are PHARMIGâ??s current value propositions for the Austrian situation, where an industry with high quality products meets an increasingly price sensitive market?**

As I mentioned before, in the years 2007 and 2008, the market grew by over 7%, and we started a negotiation at the time with the Ministers and other key players of the health system in Austria, which lasted over a year. We have negotiated a voluntary contract called Pharma Master Agreement, whereby every company in Austria with an annual turnover exceeding 100,000 Euros must participate in a common effort to give a fair share of their revenue back to the reimbursement system on a voluntary basis. The purpose of such contract was to strengthen solidarity amongst the industry.

Also, the main objective of this contract was to avoid a bill from the Parliament which would force all companies to pay around 6% of their turnover. We were anticipating such a bill and our initiative has been very successful. Today, we have a contract with the government, not a bill from the parliament; the nuance is important to us.

The first agreement lasted until 2011. We have paid 90m Euros back to the system in three years, in addition to another 90m Euros as â??old debtâ??. For you to understand the historical context in which this agreement was signed, in the years 2004, 2005, and 2006, there was a legal bill in place, obliging the industry to pay 2% of their turnover. As PHARMIG, we considered this bill as anti-constitutional, and our recommendation to our member companies was not to pay, which is a very tough position to take. I did not win a lot of sympathy at the time and it was a very uncomfortable situation, but after many cases in the constitutional court, it helped us because politicians became

more inclined to sign a contract with us in the following years.

In 2010, we entered into a new negotiation for prolongation of the precedent contract. There is today a new agreement in place, whereby the industry is paying 82m Euros until 2015, which is significantly lower than the first contract. This is explained by a decrease in the growth rate due to patent cliff. Indeed, in 2009, the pharma market experienced a negative growth of -6.3%, following by positive but low figures of 0.9% in 2010 and 2.2% in 2011. So the reimbursement system â??savedâ?? a lot money â?? which is estimated at an accumulated value of 1.8b Euros â?? thanks to this patent cliff, as many generics entered the market, pressuring down the prices.

According to the on-going contract between the industry and the authorities, part of the 82m that is to be paid over the years to come until 2015, amounting to 6.75m Euros, will be reinvested in collaboration with the reimbursement system into healthcare projects. We have created pilot projects, to which the public, as well as various institutions, are invited- mostly involving child healthcare and prevention. In the first year, we have had the submission of 107 projects for child healthcare, for which we will spend 2.25m Euros, and we will decide together with the reimbursement authorities, as to which projects funds will be allocated.

The objective of these pilot projects is to draw peopleâ??s attention to the areas in healthcare that lack either money or regulation. This is unique in Europe.

You really demonstrate a sense of anticipationâ?¦

When I started here, it was necessary to show that PHARMIG was not part of the problem; it was part of the solution. We supply healthcare. Politicians tend to use the industry as the responsible driver for high healthcare budget.

I thought it was critical to fight for our reputation, position, and recognition in the healthcare system as an industry. We are convinced that establishing a contract between the industry and the government is the best way to operate. We are not only spending money so that the system can cover the debt; we use part of this money to bring light on what can be improved in terms of healthcare services, and how it can be approved. We set an initiative. We want to reform the healthcare system by carrying out these small projects.

We are not waiting for a big revolutionary healthcare reform in Austria, because it will not come. No politician will take home this task. We have been an active player in the system. Normally, our interests go in different directions, but through these projects and through our initiatives in general, we have built a lot of trust.

**Why do you think Austria is today an attractive market for MNCs to invest in, both on the production side and on the research side?**

Itâ??s definitely not the size of the Austrian market that attracts them.

In Austria, there are excellent universities. The pharmaceutical industry is an attractive employer, hiring hundreds of people with university degree every year. The industry is also an attractive partner for universitiesâ?? academic programs.

The industry is supporting both the R&D arm and the academic arm. In addition, the pharma industry has a trade surplus in drugs, over 700m Euros, which is a consequence of having excellent staff and infrastructure in Austria.

Austria is a small country, therefore only a certain volume of clinical research can be done here. 200 to 400m Euros are invested every year in clinical trials. So what makes this country attractive? Physicians, ethics commissions and legal bodies here work in a very professional and timely manner. For clinical research, time is a critical success factor. The development of a drug takes ten to twelve years, so the sooner you have results, the sooner you are in the market.

The cooperation and understanding from legal entities in the government make Austria an attractive destination for clinical trials. The responsible people know that clinical research will support R&D development in Austria. The country is also attractive for our industry because of the support schemes in place from the city of Vienna and other regions.

**In a country limited by its size, and where the quality of its production and services is already globally recognized, what still can be improved?**

The other markets are not sleeping. Austria needs to take the right steps to ensure it stays ahead of the pack.

We can also improve the relationship between the pharmaceutical industry, academia, and public bodies. The more you work together and have a common understanding of your own needs, the better you can prepare your organization in order to meet your goals or support the others to achieve their goals.

**Where do you plan to take PHARMIG in the next 2 years, and what would be the goals, objectives, reforms, that you would like to see reached during your tenure?**

In Europe we are in a political and economic crisis. I am concerned about Europe in general. We need to create a better understanding of the public and the government about the importance of having a strong pharmaceutical industry in the country â?? or the continent.

If Europe â?? or Austria â?? wants to compete at a global level, it will not do it with low level cost. With our current system and wealth, it is clear we need to create an R&D friendly environment. My job is to explain the value of the industry, and explain that R&D â?? academia together with the business world â?? is a strong pillar to improve our economic situation. If our economics are successful, we will create jobs and taxes, and ultimately this will enable a welfare state in Europe like we have in Austria.

We need to create a much more positive picture of the industry and the economy in general. Itâ??s not a solution to work only for the state in order to have a safe job; we need to have a young generation ready to take risks, and we, as an industry, need to reward risk.

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