

Interview with Martin Peithner, MBA, General Manager, Austroplant Arzneimittel

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Can you give our readers a snapshot of Austroplant's scope of activities and its structure in Austria and the central European market?

Austroplant/Dr Peithner belongs to the Schwabe Group, the worldwide leader in herbal medicine products. It was sold to the Schwabe Group as a family business in 2009. Dr. Peithner is the market leader in the homeopathy market in Austria by a large margin.

We have only herbal products – both traditional and high tech products with full marketing authorization, Rx, reimbursed and OTC products of course. In Dr Peithner we have the full range of homeopathy products, which means single remedies and combinations products – both from DHU and Heel which are the big market leaders in Germany in those respective fields.

You are one of the first executives we have met here who is involved in the OTC business. The notion of self medication is different in every market depending on its regulation or the patient's behavior. Can you describe it here in Austria?

The OTC market accounts for approximately 15-18% of the total market. The homeopathy market is really small, accounting for approximately 1.2% of the total market. Exact market figures are not known because IMS collects data for combination products, but not for single remedies which are about 40% of the total homeopathic market and many of them are self manufactured by the pharmacies themselves.

Market growth is a little better than the Rx market, however it is still way below what we could achieve if the reimbursement system would behave differently. In Germany health insurance is reimbursed on certain criteria and indications. It's different in Austria. In almost all OTC fields, we have one or two products that are still reimbursed that comprise 80-90% of the volume which makes it extremely difficult for OTC companies to get along. For example there are still 2 magnesium products reimbursed. All the rest got de-reimbursed a few years ago so these two have a market share unit wise of about 80-90%, but at an extremely low price. You can only look for niches in areas where there is no reimbursement at all such as Cold-and Cough- products.

How is the selection made?

We don't know. Usually it's a matter of price, especially for older products. We are still reimbursed for one herbal product. We had the same price as we did in 1986 - with no increase - which you can imagine is not a good situation economically. Barring a new study or new indications, the system is unlikely to change. But even if you have new indications for the same product, your price might be lowered because health insurers would say "well, your range of patients is wider so you can sell more units." Therefore you have to go down in price.

That's a problem with herbal products because they do not have economies of scale. If you have a chemical product you can buy a jug twice as large and the difference in price is just the material that you put in, which is just 1-2% of the product. Herbals however have a linear cost curve; there are no economies of scale. If we sell twice as many packages we incur twice the costs in producing them since we need twice the plants and twice the property and personell to grow them.

As far as OTC is concerned, you mentioned the Austrian capacity to adapt itself to each situation. How do you cope with this? With the regulation you can maintain volumes but the margins decrease. In this case what do you need to do - increase production to maintain a manageable business?

Many companies went out of the reimbursement scheme and increased the price to a market level which is comparable to the rest of Europe. Our pricing level for reimbursed products is slightly below the European average. The prices for OTC products are slightly above the European average. Usually when you go out of the reimbursement scheme you can increase the price by 20-25% but it will still be below the European average.

Many companies such as us decided to get out of reimbursement with most products that are marketable as OTCs. We did lose about 40% of the volume but that was compensated by a fair price - a price that covers the cost.

Can you give us a sense of the revenue split for the group? Where does the business come from?

Sixty percent of the revenue comes from herbals, 40% comes from homeopathy. Within that 60%, approximately 70% comes from OTC.

And where do you see the most growth potential?

That is very uncertain. The homeopathy market has been flat for the past 7-8 years and growing only by price increases of 1-2% per year.

Austria has a very good and mature homeopathy market. We are the third largest market after France and Germany when you compare it to the total market and population. France leads unit-wise. Germany is first sales-wise and Austria is third in both aspects. My grandfather and several other people started homeopathy in the 1950s so we have had enough time to grow the market and have a stable base of homeopathic doctors. Our association of homeopathy doctors has more than 500 members and in 1983 homeopathy was officially included for the first time in the law as a medical product. Today there is not a big discussion between homeopathy and allopathy - it's just part of mainstream medicine. It's not reimbursed.

What do you see as the next steps to get it onto the reimbursement system? Do you see it as possible?

No. Homeopathy products are excluded from reimbursement by their own law. They are not reimbursable no matter what. However, it is not a big problem because the typical single remedy product costs approximately the same price as an average copayment.

If you get a reimbursed product, you have to pay a copayment for every package. It's a fixed amount - currently 5.30 euros - which you have to pay regardless of what the product costs. Officially we do not have a copayment because formally it is defined as a tax. That is also the reason why the numbers you get from industry or IMS are completely different from the ones given by the health insurance system.

For example, if the health insurance system says that the cost for medicine is 2.4 billion euros, it is because they did not deduct the copayment and the sales tax from that number (sales-tax is refunded by the ministry of finance). We say that the cost to the community for health insurance is the cost of the medicine minus the cost of the copayment and sales-tax. A normal patient has to pay the copayment which is very close to the price of a single remedy. So it doesn't make a big difference for the patient whether they buy it themselves or get it reimbursed.

You are on the board of Pharmig, which essentially covers the entire pharmaceutical and healthcare market here in Austria. The board is well diversified. What are the specific issues that you would like to bring to the table or the reforms that you would like to see achieved?

In my specific field there are two European problems. One is pharmacovigilance fees in Europe. EMA is proposing fees of 80,000 euros per PSUR plus a fixed service fee. Excluded from that are generics, homeopathic registered products, THMPs, and well established products. There is an article in the guideline 2001/83 that says that on a national level countries can have full marketing authorization over homeopathic products, including indications and low potencies. In Austria we have more than 400 of these full marketing authorizations. So they have to pay the fee. Of these 400 marketing authorizations there are only 32 that make revenues of 80,000 euros or more. You can imagine it would be the end of all of these products.

The second problem is the borderline issues currently being discussed in Europe concerning food supplements with herbal ingredients as opposed to traditional herbals and well established herbal products. It's a major issue all over Europe. There are some countries that have completely open markets. Funny as it may seem, the UK as a traditionally very liberal market was the first country to start the discussion about THMPs because they had thousands of products on the market as food supplements and many of them were really dangerous. It led to dozens of deaths every year because nobody knew what types of toxic plants they really contained. It was a major issue in the UK because they had no registration procedure for herbal products so all of them went into the food supplement market.

Something similar occurred in Italy and they needed some sort of regulation to get these products under control. The UK started the discussion and a few years ago the THMP guideline was implemented.

It works very well in Austria. Our registration offices are very pragmatic, a lot know how about homeopathy and herbal products and because of that the procedures are reasonable, quite cheap and quick. It takes nine months for registration as a traditional herbal product. It works fine in Germany as well but not at all in France or Italy.

On the opposite side, Italy made a list of more than 1,000 herbals that are allowed as food supplements because they ask for prohibitive fees for the registration as a THMP. Lots of issues will come up with that and some of them are really dangerous.

For example, a certain plant was used for thousands of years in Europe as a tea. In the 1980s a woman from Switzerland collected it and concentrated the tea for consumption. Two weeks later

she was dead. Many plants contain toxic substances that you can hardly detect as long as you take it the traditional way. But once you start concentrating it, the toxic substances become more concentrated as well. Officials found out that these plants contained pyrrolizidin-alkaloids, some of the most toxic substances in nature. A few micrograms of it can kill you. All plants containing these substances have been forbidden in Europe ever since then.

There are dozens of products on this Italian list that are potentially toxic, especially when you use extracts and not the tea. Many are completely harmless as long as used in their traditional form. But we do not know what substances are in two-thirds of them.

However, the food industry has a major lobbying activity in Brussels right now and the commission is under considerable pressure. There is a discussion paper asking whether the evaluation should be kept as is, or if a completely new group of products should be implemented which would be really dangerous. We are fighting against it. Even people in our ministry who are responsible for food supplements and the Heads of medicine-agencies think the current procedure should be kept.

It's interesting to see that these topics issues are more at the international level.

There are very few national issues left except for reimbursement. The rest comes from Europe. We currently have a big issue in Austria. There is a proposal for a new medicines act that will allow internet trade with OTC products.

Are you in favor of it?

No, I am absolutely against it because it would completely ruin the pharmaceutical system in Austria. Every country has a tradition of pharmacies for providing medicine to their patients. But it's a very sensitive system and if you take one straw out the whole system collapses. That's exactly what would happen in Austria.

In Germany, for example, you can open a pharmacy wherever you want. You do not have to apply for it, there is no concession, there are no boundaries or distance to the next pharmacy that you have keep. What happened is that the pharmacies concentrated in the downtown areas and there are very few left in the rural areas where the elderly - who need medicines the most - live.

In Austria we have a system where you have to keep a distance of at least 500 meters between the next pharmacy. You are also not allowed to open a pharmacy if you set it up in the area of an already existing one and cause it to serve less than 3,500 people.

Are there many independent pharmacies?

All of them are independent. Chains are prohibited and because of personal liability issues a pharmacist has to own at least 51% of the pharmacy.

Do you still keep the same level of excitement as a part of the group when there is no more ownership?

Absolutely. I love my job, I love what I am doing and this has not changed at all. The new owners leave me alone in the day-to-day business and the business strategy is developed on a very open basis. They learned in the past that the company is running very well and that we do have the right strategies to keep the products on the market. We have a little more bureaucracy and can use quite a bit more resources that we did not previously have such as the legal department when it comes to international contracts.

And your focus is on the Austrian market only?

Yes. We do have operations in the Czech Republic, Slovakia and Hungary but I have a partner who runs the export business.

Where do you see the company moving ahead? Where do you want to take the company in four to five years?

I want to keep us in the market leading positions that we currently occupy, but it won't be easy. Think of the borderline issue. It's a European topic and when you look at my CV I have been involved in AESGP for at least 10 years now. I am often in Brussels and London for these meetings and I keep in contact with the European Parliament and Commission to lobby them to keep things simple.

Just last year we had a problem with a pharmacovigilance data base. It was planning on aggregating all products into one common databank. The problem with homeopathy is, if you do that, you have 2.3 million data sets - for my company alone - which equates to 6.25 man years of work to just type in the numbers. In cooperation with the AESGP and our agency this issue could be resolved very quickly: Registered homeopathic products do not have to be filled into the database.

The issues that we fight with are European by nature and not national issues: the borderline issue, food supplements and the question of who will bring pharmaceutical herbal products to market if you can make the same product with fewer claims.

If you can sell the same product as a food supplement with a claim but without registration, GMP or pharmacovigilance, who would still go for a registration as a traditional herbal medicinal product?

That would be the absolute end of herbal medicinal products. Nobody would spend another euro on R&D because you can never earn it back. Why would you invest R&D when you can spend the same amount of money in marketing and no product development anymore?

If you look at today's pharmaceutical market, the base molecules for 70% of all medicines on the market come from plants. Nature is quite creative in doing things, even tracing its roots to penicillin in the early days. This would be gone if R&D stops in the herbal area. If we stop science in this area, it would be a major loss.

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