Interview with Ronald Pichler, General Secretary, FOPI

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Could you give our readers a snapshot of the association and its role in the Austrian pharmaceutical context?

FOPI is a small and specialized industry association that has a homogenous membership structure. This structure is based on regulations in its statutes and our understanding of being a purely R&D Pharma focused association. For applying companies, there is a threshold of 90 percent of the group turnover which must come out of the sales of patent-protected innovative drugs. This clearly shows the main objective and topics that FOPI covers – it is all about innovation, research and development. It is about the framework and requirements that we see for having innovation understood and lifted up in Austria from research to retail. This is where FOPI is active and focused. FOPI is an association without any dedicated resources; everything is being done by members on top of their normal responsibilities in their respective membership companies. In the last two years, there has been an incredible increase in the activity and engagement of FOPI. This might be a consequence of having a new structure with clearly dedicated responsibilities in which every segment is clearly aligned with personal responsibility from a specific general manager of a FOPI member company. This means that FOPI has a working group structure, with working groups dedicated to innovation, bio-similars, and so on. Each working group is led by a general manager which in turn creates a very good level of commitment and personal engagement. While FOPI is only one voice in the big choir of voices in the Austrian healthcare system, over the last two years FOPI's profile has been sharpened. I feel that almost everyone in the Austrian Health Care System now is aware of FOPI and its representation of the interests of the R&D-focused pharma industry, as well as its partnerships with other associations, such as the Austrian Chamber of Commerce, and also Pharmig. The big difference between FOPI and Pharmig is that FOPI has a clearly dedicated innovation focus. Having said that, Pharmig often has aligned positions with FOPI, because everyone has the same issues in the business. We all face problems with getting innovative drugs reimbursed, or having the appropriate framework with pricing, and we are addressing these by various means, also by being active in events such as Alpbach, the main stakeholder event and European forum in Austria. FOPI does its own outreach by holding meetings with key political stakeholders, stakeholders from the payer world, and communicates via position papers. It is the normal work of a small, but focused association.

How does FOPI position itself in the Austrian pharma landscape? Does it contrast with Pharmig? How different are your opinions?

From our 24 members, 23 are also Pharmig members, so there is a big overlap in the membership structure. Topics which are of relevance for the whole industry are clearly addressed by Pharmig. However, regarding innovation, topics and questions about how to get innovative drugs reimbursed, the added value of innovative drugs, and how the benefits of innovative drugs should be remunerated by the payer system, are where we build up our positions and align as far as possible with Pharmig. The more associations that stand behind a position, the better it is in the sense of actually implementing a commonly accepted solution. There are some areas that are really dominantly important and relevant for FOPI members, and it has always worked out well to define our respective positions. For example, the European Commission recently issued a draft for a revision of the transparency directive, which is of utmost importance for FOPI respectively the FOPI member companies. The organization built together a position in a working group in order to make its voice heard in the outside world. FOPI drafted a position and aligned this with Pharmig. In other areas, such as policies on the use of generics, FOPI might come to specific conclusions. Generally, both industry associations cooperate wherever and whenever possible for the sake of the Pharma industry in Austria as whole.

How is research accepted or recognized and valued in Austria? How does it compare with other countries?

When I say framework for innovation, I am implying that Austria needs appropriate conditions for innovation from research to retail. When I talk about research, I am referring to some excellent biotechnological companies here in Vienna. GlaxoSmithKline for example cooperates with some of these biotech companies, whom we are very happy to have here. When I look at this biotech cluster in Vienna, I conclude that obviously the conditions are quite fine in Austria. We have a situation where promising assets like that can be born and developed in Austria. However, when I talk about retail, meaning the ability of the system to get innovation into products and get the benefit and value of the products to patients and consumers, there are huge barriers. I am talking about market access becoming more challenging, and the sometimes near impossibility of getting innovation to the Austrian market due to a series of issues. For example, when you bring an innovative product to the Austrian market, the system may ask for a price applying a comparison level with a similar product that is already generic. The comparison level applied it not at ATC 5 but ATC 4 level, meaning not identity of substance but similarity of substance. In other words, innovative companies are being asked for a price which is on the generic price level of a similar substance, and this can be very challenging. Even if the Austrian company would like to offer this price, it would have to ask for approval from the respective headquarters. To get such a price level approved, often turns out to be impossible for the second big reason; the system of external price referencing. Price levels are very low in Austria, and the maximum price you can achieve is the EU average price, but this is only the maximum price; this is where you start the negotiations. It is about your ability to demonstrate the value and benefit against the comparator that is being chosen. And there are situations in which an innovative product is being compared with a similar generic substance. That is a clear hurdle for innovation.

Another example: When you have a product in the market, it is reimbursed, listed, everything is fine. Then – after new investments in R&D – you come up with a new indication for the same product. The rule in Austria is that you have to decrease your price if you provide more benefit which is not, in our opinion, so logical. It is also a negative incentive for doing more R&D on an existing drug. Against this background, the question “Should there be any further investments in R&D in that drug be done?” is a very critical one. In the past, further R&D leads to the conclusion that a particular drug has other benefits. If you have such a negative incentive as the described price regulation for new indications, you are being punished if you demonstrate additional value; which seems illogical.

Another example is biosimilars. In Austria, biosimilars are regarded equal to generics when it comes to the definition of the appropriate price level. The price rule that is applicable for generics is applied to biosimilars as well, yet they are two totally different things in our view. As we have discussions within the industry and with partners outside of the industry, some producers say that if Austria really requires a price level that is at a similar level to generics, there is fear that new products simply cannot be brought to the market.

What will the future look like for research, and do you think Austria will maintain its attractiveness?

There is a difference between research being made in the biotechnological industry where small start-up companies with an academic background focus on specific assets, and the big pharma R&D world. Regarding the biotech world, I honestly see a positive future for Austria because I see that the conditions are quite attractive for the biotech industry here. In general, I think it is an interesting and promising environment. Conversely, the big pharma R&D is currently undergoing a deep change. The profitability and efficiency of big pharma R&D is being challenged more and more, and it is becoming more a question of cost and economies of scale. Where do you have really simplified possibilities to engage an efficient and sufficient number of patients in your R&D

activities? I must admit, Austria unfortunately does not seem to be the number one market for R&D. Firstly, a low number of inhabitants means a low number of potential patients that can be enrolled in a program. Secondly, there is the framework challenge regarding the speed of getting a program into place. Thirdly, there is cost. When you see where the increase in R&D investment really takes place, you come very quickly to the conclusion that it is the emerging markets. For these three reasons, it might be more attractive to invest in these emerging markets than it is to invest in Europe. This is a challenge. I also see that big pharma does not necessarily perform all the R&D steps everywhere independently. This means that more and more partnering is being done between big pharma and small biotech companies, where the pharma company provides financing and know-how, and the biotech company can do focused work on their asset. If it turns out to be an attractive product, the big pharma company gets the right of exclusive marketing for the product. There is also a question of diversifying the risk and of increasing the portfolio. It is not necessarily the case that big pharma has to do everything on its own. In summation, in Europe, I see significant challenges for R&D activities of big pharma. Even though, Europe of course will maintain important and relevant for Pharma R&D.

As the General Secretary of FOPI, what are the objectives you have set for yourself in the next few years in the medium-term?

In the medium-term we would like to see innovation acknowledged and rewarded in an adequate way. In the last couple of years, there has been a tremendous cost consolidation program run by the payer organizations with the backing of the federal government. This was a success, especially in regard to pharmaceuticals. The targets were achieved or exceeded, and now I would like to see “headroom for innovation” being materialized. This means that with this ongoing cost-consolidation program, considerable amounts of money are and were being saved. Now we are thinking that it would be appropriate and in the best interest of patients in Austria that this saving potential is being directly used for increasing innovation in Austria. This means to really spend and invest in innovative drugs in Austria. We saw a significant increase in the use of generics, a broad achievement of the goals of these cost consolidation programs but now it is time to spend again on the areas where investments are needed. Currently, the situation involves only focusing on the benefits of an innovative drug in quite restricted areas of the reimbursement sector. Any positive effects that an innovative drug can have in the hospital sector are not being adequately considered by the system. This means that when you come up with a new innovative drug that saves a patient several days in the hospital, it is not appropriately acknowledged, paid for, or remunerated within the Sick Funds system. I would like to see this changed. From a macroeconomic point of view it does not make sense to only focus on one area, we need an overall approach that allows to maximise the benefit from an innovative drug for the patient and for the health care system in Austria. The benefits of innovative medicines cannot be realized or seen when only focused on a very restricted area.

In the last two years, FOPI has established a well-known profile and has made clear what it stands for through its various tools and activities. Now individuals are aware of FOPI and it is time to get into the second phase, especially in these areas of difficult economic situations, to make clear what innovation can bring in terms of benefits for the patients and the country. This is what FOPI stands for.

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