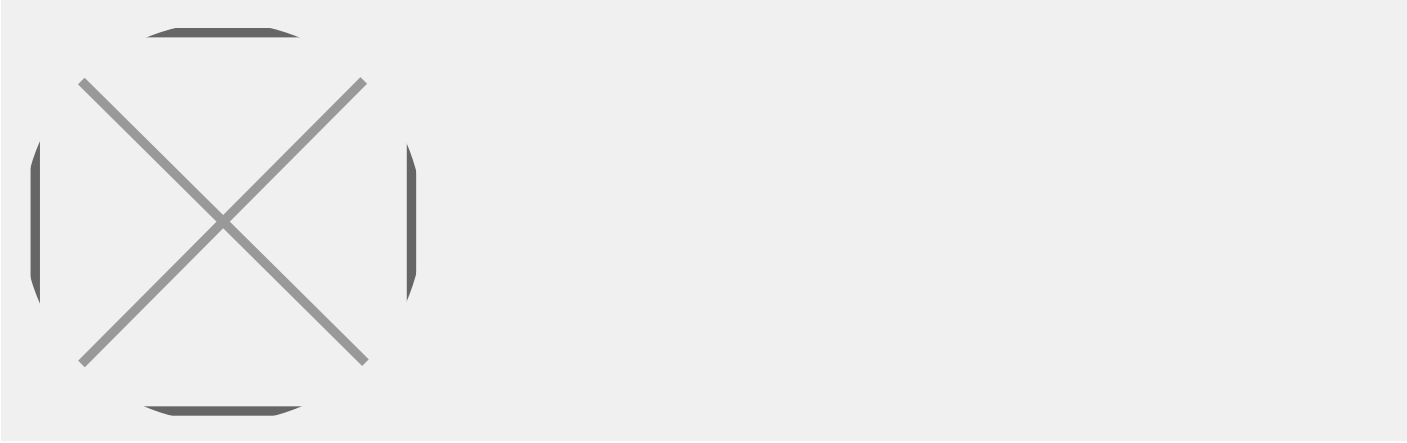
Interview with Tamàs Dàvid, Deputy Director & Market Access Specialist, Association of Innovative Pharmaceutical Manufacturers (AIPM) Hungary – Innova



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With various new government measures, the pharmaceutical and healthcare sector in Hungary has been undergoing quite a turbulent period recently. But if we first take a step back… Can you explain to our readers what has attracted most of your members to have a presence in the Hungarian market?

V.N.I.: Traditionally, there are a number of strong local pharmaceutical companies present in Hungary. However, these companies are mostly generic players. Of course, the patients need innovative medicines too.

Also, I truly consider the Hungarian medical doctors as well trained people. At present, there is a tendency towards the centralization of resources in healthcare in Hungary, particularly in areas such as oncology, haematology, cardiology and a number of other therapeutic fields. This is a key advantage to conduct large-scale clinical trials.

In this respect, Hungary has been quite an attractive area for MNCs to be present in.

Yet the government measures have also impacted clinical trial activity in the country. Do you still find the environment attractive to conduct clinical research here?

D.T.: From what I know, the numbers of growth in this area are decreasing. When you look at R&D in particular, the environment has become less favorable. Companies now feel less incentivized to invest in research in Hungary.

V.N.I.: However, once a trial is being initiated, it obviously already takes many years before it is actually completed. Yet, I have still seen many companies bringing clinical trial activity to Hungary, because they need patients. There is a required number of patients for every trial. To strengthen the trial's statistical power, MNCs recognized the need to include the Hungarian patients too.

According to you, what have been some of the key milestones in the evolution of the Hungarian pharma market?

V.N.I.: The healthcare government has always been closely watching the expenses on drugs in Hungary. The pharma-economy law in 2007 was the first measure that resulted in the withdrawal of the first set of funds from the healthcare system.

The real value of the drug market has always been increasing by a few percent over the years. It is very important to point out that the Hungarian population has access to innovative drugs. Of all innovative drugs worldwide, 90 to 95% are available to patients in Hungary.

There are always new drugs lining up and awaiting reimbursement, for which the average time for approval is longer than in the Western countries. Still, sooner or later, the most important drugs will be accepted.

Despite this high percentage of innovative drugs being available in the market, is market access still a challenge for some of your members?

V.N.I.: It might be a challenge at the moment because of the shortage of funds. But now, we have tried to change the mind-set of healthcare decision makers in terms of the price of generics. We wanted to convince policymakers to bring down these prices as they were very high in Hungary. In the long run, this might provide more room for reimbursing innovative drugs.

As you already mentioned, in terms of industry, the Hungarian pharma sector has traditionally been fairly focused on generic players, with local success stories such as EGIS and Gedeon Richter. In your view, what did the increasing presence of innovator companies bring to the Hungarian patients?

V.N.I.: The generic players are not able to provide the entire spectrum of drugs that are needed to treat more sophisticated diseases. Generic drugs are mostly used for very common diseases, such as hypertension, diabetes and so on. There are very sophisticated drugs too, such as monoclonal antibodies. MNCs, in turn, provide innovative medicines that interfere with the molecular biology of the cell, combined with subcellular structures. These medicines are essentially providing more

sophisticated approaches, for example in tumour therapy.

Apart from the patients, innovator companies generally also have a key role to play in supporting the country's medical community. How strong are these ties in Hungary?

V.N.I.: Most innovative pharmaceutical companies have managed to establish very strong ties with the Hungarian medical doctors, especially with leading experts in the field as well as expert doctors in various parts of the country, beyond the capital city. These companies have been providing congress participation for these experts, which has been very important in ensuring continuous medical education for the Hungarian medical community.

Does this mean that rural access to medicines is also less of an issue in Hungary, both in terms of patients access and company penetration?

V.N.I.: I do not see this as a big challenge, as the rural access issue relates more to the level of the GPs, polyclinics and primary care. These provide care for the very common diseases. Once they diagnose a disease that belongs more to a centre, the patient will be referred to such facilities.

As you mentioned before, there is a pool of talent available for clinical research in the country. What is your take on the availability and the quality of human capital for MNCs in Hungary?

V.N.I.: The labor market is very good. Because of the low wages for doctors and pharmacists, a lot of Hungarians with medical backgrounds will prefer to select and go work for an international company instead.

Do you feel that there is a certain preference from Hungary's medical community to prescribe innovative medicines over generics, or the other way around?

V.N.I.: This really depends on the type of doctor. General practitioners (GPs), for example, are used to dealing with very common diseases. When it comes to more sophisticated types of illnesses, patients will be treated by specialty health centers. These centers and hospitals in general are more used to using innovator drugs.

Moreover, there are some therapeutic areas, such as orphan drugs, where there is only one drug on the market for a certain type of disease.

The government's Széll Kálmán plan has been described as a welcome step towards growth and sustainability by the IMF's January 2011 Article IV consultation. However, late June 2011 a lot of measures had not yet been implemented. The industry was unsure about the unpredictable environment with regards to what measures were going to take place. In a brief outline, what are the key government measures that have already been implemented as part of the plan, which directly affect pharmaceutical companies and the healthcare system

in Hungary?

D.T.: The Széll Kálmán plan is a structural reform which affects 7 important territories and the healthcare budget is one of them. It proposes significant decreases in the drug budget by Ft. 83bn next year and additional Ft. 40bn the year after.

We have had many talks with the National Health Insurance Funds and the Ministry of Health,. What is clear is that the money has to be saved. We now need to cooperate to ensure that further resources can be saved.

To provide you with a little background on the pharma industry in Hungary, it needs to be said that the interests of the sector are significantly divided.

There are currently four associations for the industry, consisting of the AIPM, MAGYOSZ, the Generics Association and the Hungarian Vaccine and Biotechnology Association (HBA). The two main Associations are MAGYOSZ and AIPM. MAGYOSZ member companies are the traditional Hungarian drug manufacturers who are generics, meanwhile the innovative companies' association is the AIPM.

To prevent a reduction in the prices of generic medicines, MAGYOSZ has been actively lobbying to increase pharma specific taxes. AIPM, on the other hand, has lobbied for a reduction in generic prices since the innovative prices are already the lowest in all of Europe while generic prices are higher.

In preparation of the suggested government measures, every association brought their proposals to the table. AIPM considers its efforts as successful, as most of the association's proposals were taken into account.

The decision makers at the Ministry and the health insurance funds have clearly taken note of our concerns and our messages. They understood the reality and our claim that generic prices in Hungary are too high, that's why that is the only territory where further savings can be achieved in order to decrease the budget and maintain the access to the newest innovations.

The measures that have been taken can be grouped according to financial measures and structural reforms. On the financial front, three key steps have been taken by the government.

First, the sales tax on the reimbursed part of prescription medicines has been increased from12 to 20%. Second, government has increased the sales representative fee that companies have to pay annually. Previously Ft 5 Mn (roughly USD 25,000), this fee has been increased to Ft 10 Mn (roughly USD 50,000) per representative per year. The third measure that has been implemented is the price-volume agreements, which has lowered the threshold of the volume of reimbursed drugs by 10%.

There were also “structural reforms” which affect only certain companies. There are about 8 measures of which some have been implemented already. The most important structural reform is the new generic program which introduced the so-called “Generic Price Corridor” where prices of off-patent drugs are set by blind bidding. Whoever exceeds the lowest price by 5% loses 15% of the reimbursement. This measure applies to reference price groups and therapeutic reference price groups for normative reimbursement (drugs that can be prescribed by GPs). Specialists’ territories are not involved. This measure alone will generate more savings in 2012, than than the tax increase.
The second most important “structural” reform was the recalculation of the reimbursement of combinations. At the moment, it is calculated by taking the lowest price of the components and the lowest reimbursement of the components, upon which the gross reimbursement price for the product is then calculated.

Which measures are yet to be implemented in the future?

D.T.:
One of the most important measures is the transfer of drugs from the outpatient budget to the inpatient budget. Shifting this decrease in drug budget to an increase in the hospital budget is acceptable for government because it corresponds to the Széll Kálmán objective to decrease the drug budget. If this measure works out, it will possibly generate “savings” of roughly Ft 30 Bn to Ft 40 Bn, or 10% of the total healthcare budget. In order to make it work, money should also be transferred to the hospital budget.

Further to this, I think we have been successful to say that we will not be able to decrease the drug budget by 25-30% if we want to remain at high level standards of pharma and drug supply. The political message is that co-payments cannot increase. For the drug budget to be lower, this means that the pharma industry must pay more but of course, we cannot. This is the problem we are facing today and that’s why measures like the retail hospital drug transfer can be a compromise. It fulfills the government’s drug budget cut plan and maintains the drug supply, but of course, it doesn’t generate significant savings on the Health Fund’s level. This measure alone generates half of the proposed savings for 2012. We think, that using the transfer instead of further restrictions is an admission of the fact, that the proposed budget cut cannot be implemented
Since July 1st 2011, as a result of the increased sales rep fee and the sales tax increase, every company had to revise their operations and over 300 people have already been laid off over summer, which number will be increase by the end of the year. In Hungary, AIPM members roughly employ 3,000 to 4,000 staff. The rate of the reduction is high, but the government sees the procedure as the tool, which will treat the Hungarian health care’s human resource problem.

In my opinion, the sales and marketing reps were the ones leading the operations in the past. This is a paradigm that is now bound to change, whereas market access, public affairs and key account

expertise is expected to become more dominant.

If we look at the future for the pharmaceutical companies themselves, what is still attractive for them in the Hungarian market?

D.T.:
The positive aspect is that there is still place for drug reimbursement and the measures suggest that the Hungarian government does not want to send the innovative companies away. Everyone has the desire to keep multinational companies in Hungary but actually, there is no room for growth.

I hope that the insurance system will change, as the current system is not sustainable. It would be good to push the government towards involving more private insurance companies. Indeed, if patients pay more money, they should be entitled to get innovative drugs. However, this might not be well seen by the voters since it had been contested by the ruling party in the past.

Do you feel there are more opportunities for the local companies than the MNCs?

D.T.:
The generic players have been very successful in the past 20 years and have managed to make the decision makers understand that if the prices of generics were lowered, they would have to lay off half of their employees.

One third of the generic market is owned by the MAGYOSZ companies – Teva, Egis, Richter and Sanofi, and 60% by the foreign importers. The way of thinking is very nationalistic so multinationals are always seen as “foreigners”.

MAGYOSZ successfully lobbied with the government that many of the nation’s needs can be met by the local companies alone. This is when AIPM came in to clarify that they can indeed produce all the generics needed, but not the innovative drugs. Moreover, generic players do not bring real R&D activities to the country.

Which of the multinationals are now manufacturing in Hungary?

D.T.: GSK and Sanofi are manufacturing through Greenfield investments, while Servier is particularly involved in R&D.

In your view, what is AIPM’s greatest achievement for 2011?

D.T.:
Our greatest achievement this year is that we were able to change the government’s mindset toward us and eliminate a 20 to 30% price cut at the beginning of the year. It is something that we have been able to avoid. It seems that we can maintain this until the end of the cycle.

How do you think the market will be in the future? What will have changed?

D.T.: I think that we need to change things or the situation will stay the same. Measures must be taken.

Doctors are leaving the country, because their salaries are only around EUR 400 per month. The younger generations are leaving. The government sees this is a big problem, but it does not have the money to raise the salaries either. A number of months ago, the Ministry of Health started a program in which residents can sign a contract and commit to stay at least 10 years in Hungary. Such signature implies that these people will receive around EUR 300 to 350 euros a month in extra. Out of 600 resident doctors, only 100 signed it. It clearly shows that the rest are not committed to staying under the current circumstances.

If nothing changes, there will be no growth and big problems. In the private sector, it is the same. You need at least 5 years to build your reputation and knowledge and this requires a lot of money.

V.N.I.: It is our expectation that the market will be the same in 2012 as in 2010. I would not dare to predict the size of the market, but I do think that the aim of this government is to stabilize the whole economy of the country in the long run. Once we are there in a few years from now, every sector will find more stable markets in this country.

I also remain optimistic about the external environment, as I have a lot of faith in the current government. At present, there are currently 160 hospitals in the country, a number that is too high for a population of only 10 million people. I am therefore pleased that the government now has the green light to further rationalize healthcare in the country. If done right, Hungary’s healthcare system is set to become more transparent overall. Patients will have more clarity as to which level of healthcare they have access to, and how they can receive definite care. I remain hopeful that this reorganization on the healthcare provider side will be completed by the end of the current cycle.

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