Interview with Alp Sevindik, Secretary General and COO, AIFD â?? Association of Research-Based Pharmaceutical Companies

20.08.2012

Tags:

AIFD â?? Association of Research-Based Pharmaceutical Companies

In an environment where the line between generic and innovator companies is less and less relevant, due to the growing trend of innovators integrating generics products in their portfolio through acquisitions, to what extent has the role of association evolved?

Despite the growing trend of integrating innovative products with generics, the role of the association has not changed much. This does not change our function and role very much because since the beginning, as an association, we were concentrating on the issues of innovative products, although our members may have recently increased their portfolio mix.

Nonetheless, our activities and interaction with the government has increased considerably. This is because the government is now handling pharmaceutical spending more centrally, especially in the last three years, in line with the concept of global budgeting. In fact, having joined the association approximately two years ago in 2009, I have been deeply involved in these interactions with the government. Even so, our aim remains to represent the association as it always was; that of the innovative industry and products.

You are COO and Secretary General of AIFD since 2009, and have witnessed an industry facing increasingly tough government measures coupled with a difficult economic context.

As the bridge between the government and the industry,
how challenging is your position, torn in between being a partner of the government and helping it control the cost, and defending the interests of the industry? What have been the most important files since you started your tenure?

I think it has indeed been very difficult in Turkey. From the governmentâ??s point of view: for managing the budget, but also from the industryâ??s point of view: for financing the higher consumption of pharmaceuticals due to Family Practitioner system which increased patientsâ?? access to healthcare.

As you may know, as a result of the local economic crisis undergone in relation to the global crisis, peaking at 2009, the government was taking certain measures with various sectors and industries to control and cut costs. In 2008 pharmaceutical spending was approximately 1.35% of GDP, and suddenly in 2009 it rose up to 1.6%, which seemed very high to the government. Interestingly however, this increase was mainly a result of the shrinking GDP level. Despite this, the government

decided that this was not sustainable and decided to implement budget controls to help it manage the crisis situation and therefore imposed some new measures which brought on spending and price cuts.

We can say that from the beginning of this global budgeting period, until its expiration in 2012, the innovative products have been hit by around 34% reduction in price plus around 18% of TL devaluation against the Euro which still needs to be resolved. This is something quite uncommon in Europe or elsewhere in the world, negatively affecting the patients, pharmacists and the industry in Turkey.

Although 2013 represents a new budgeting period, we expect that the government would like to continue the budgeting trend which allows it to control the pharmaceutical budget and make it more predictable. Although we support increasing the predictability of the pharmaceutical budget, we have to acknowledge that the budget that was set since the beginning was unrealistic not reflecting accurate macroeconomic data and assumptions. For instance, the government had built its budget based on 4 â?? 5% growth rates; however, we had actually realized growth levels of 8 â?? 9% and this was not incorporated in the current budget model. The fundamental problem, therefore, is that our budget has not been revised to account for these new macroeconomic indicators and changes and it never reflected the Governmentâ??s increased provision of health services to the patients of Turkey.

Another issue that requires attention relates to the pharmaceutical pricing decree on how exchange rate differences should be reflected to prices. The Turkish pharmaceutical pricing system references lowest European prices. The Turkish Lira exchange rate with the Euro is not fully representative of current price levels. The applied rate is 1.9595, while it is in fact currently around 2.33, with 18% difference which requires the implementation of the pricing Decree.

Another area that could be addressed through a revised and improved budget in 2013 relates to new and innovative product introductions which have been minimal in Turkey. A substantial number of new products that have been approved by the FDA or the EMA since 2005 are still not available in Turkey. I think the Turkish patients need those new products. That is why in the new budget period there should be a different approach towards patientsâ?? access to new products in Turkey.

Despite some unpleasant features of the current pharmaceutical environment, we are now coming to an end of this budgeting period and are looking into how we can correct this in the 2013-2015 budget period. Our first meeting to discuss this with the Social Security Institution and the Ministry of Health was a positive one where, unlike before, all of the relevant stakeholders were present, including three associations representing the industry and the Turkish Pharmacists Association. Obviously, this creates a much better environment that will allow us to build a more rational and realistic budget and discuss the system for a sustainable financing of pharmaceutical spending.

You denounced the governmentâ??s practices to be economically, and commercially inacceptable, and deplored that rational and sustainable solutions could not be found. What would be AIFDâ??s solutions and propositions to help the government control the cost or define a new healthcare model?

Of course, there are many issues and topics that need to be discussed and examined, and some of the most pressing issues that require our attention and that of the government are as follow.

First, the government has set the healthcare expectation of the population at a very high level. The populationsâ?? access to healthcare has increased tremendously in the last nine years of this governmentâ??s tenure. In 2002, Turkish citizens would visit a doctor 3 times a year, on average. However, the numbers of visits have now risen to 8. Of course, most of these visits result in a

prescription. Hence, one of the problems we are currently facing is government induced volume or demand. If the government wants to provide this level of quality of health service, the volume of medicine usage will expectedly increase and accordingly, so should the budget to account for that. Unfortunately, that has not been the case however. Even now, in the 2011-2012 period, the increase in the number of people prescribed is 4 million.

Therefore, we think volume control is a must. This brings us to the topic of rational drug usage under which there are many measures that can be taken. One is obviously to enforce therapy guidelines and link them with the reimbursement system. This is currently not being done. Another way to address this is through adjusting â??co-payâ?? programs. We have been discussing these for many years and have only begun to be introduced since last year. Nevertheless, although this measure is quite successful at controlling the overall volume, it is not sufficient. I believe that levels of co-pays should be differentiated based on the severity of the disease rather than the medicine itself. These are but a couple of the measures that can be implemented by the government to address this issue and we hope to further discuss these with them in near future.

Another issue to address relates to predictability, which I believe is very important. More specifically, I am referring to the decree that relates to the exchange rate differences that we have been experiencing since July 2011. Since then, this decree should have been implemented and the exchange rate differences should have been applied to the prices. We hope in the new budget period, such decree or regulations will be obeyed by all concerned parties.

Of course, the government has made significant efforts to attract investments into Turkey but we feel that the pharmaceutical sector lacks the environment to attract these investments. Therefore, the government should address the issues relevant to attracting more pharmaceutical investments into Turkey in order to develop the local R&D and production sectors. We are happy to see the Government moving in this direction within the initiative to develop the Pharmaceutical Sector Strategy Document. Of course, this will require an improved environment. I would say that the pharmaceutical industry is a very strategic one and can help this country a lot.

AIFD has initiated a strategy report to showcase Turkeyâ??s potential to become a regional centre. Sanofi, Merck and GSK have already moved their regional centres to Istanbul, which will incentivize other MNCs to do the same. What will be the main lines of this report to attract further investments, and highlight Turkey as a place to invest as opposed to a place to import despite harsh market conditions?

At the moment, Turkey needs to have a strategic outline that will help increase the predictability for both the government and us. As a result, we have put together this strategic document, which also celebrates the Turkish Republicâ??s 100th year anniversary, and have called it the â??Vision 2023â?• study. Within this report, we focus primarily on three strategic areas which we believe will help develop the Turkish pharmaceuticals industry. Also, the Ministry of Science and Technology has taken the initiative to attract greater investment in the pharmaceuticals sector by inviting all stakeholders to participate in workshop discussions and I believe our vision 2023 is very fitting to this.

More specifically, one area of focus in our study is concerned with increasing the level in R&D and clinical research. The clinical research funds that Turkey is currently attracting is minimal; no more then $50 million, compared to the nearly $100 billion clinical research ongoing in the world. Obviously, we would like to have a greater role in this international market. This could ultimately also contribute towards reducing Turkeyâ??s trade deficit. I believe that the key to addressing this issue lies in improving the investment climate, given that Turkey already has the human resources, universities and overall infrastructure to facilitate the development in R&D.

Second, our report is also dedicated to increasing and developing pharmaceutical production in Turkey. Currently, 80%, of the pharmaceutical products consumed in Turkey, in unit terms, were actually produced in Turkey. However, if you look at monetary terms, this 80% represents only 45% of the value consumption. The remaining 20% of consumed products represent 55% of the value consumption. These include critically more important products like biotechnology, oncology and diabetes related products. In order to reverse this situation, we need to incentivise the local environment to attract the high tech industries to Turkey. This is something we have addressed in our report.

Third, the study intends to outline how we can transform Turkey into a major management hub as in the company cases you mentioned. As Turkey becomes somewhat more and more influential in its region, we are looking to attract more regional management hubs into Turkey, which can further enhance its regional stance and increase its service exports.

Overall, in order to achieve this goal, we are taking a flexible position as we are in discussion with the relevant stakeholders rather than merely accepting or rejecting proposals and that is why we are optimistic. Moreover, we also believe our member companies can contribute to achieving this vision and I believe that the Turkish pharmaceuticals sector needs this contribution.

Turkey has long been a place for industrial investment by MNCs, nevertheless there has been very little done on the R&D front. How do you explain this, and do you feel that your members are willing to change this trend? In your view, can Turkey become a host country for global R&D activities?

Ultimately, I believe that this will be determined by the governmentâ??s decisions that we expect to have by the end of this year. However, we have already seen some promise in this area considering the Turkish governments plan to participate in Juneâ??s Bio conference in the United States. I think this is a good and important step forward as it will allow the Turkish government and the Bio industry to get better acquainted, so to speak. Another promising development, as mentioned earlier, is the Ministry of Science and Technologyâ??s plan to develop and issue a strategic document outlining Turkeyâ??s pharmaceutical advancement. This will certainly help improve the predictability and direction of the industry.

Finally, I am confident that Turkey has the potential and all necessary human resources as well as facilities to attract increased R&D activity, along with developing its own R&D. Of course, we are ready to contribute in the entire R&D aspects, from clinical research to basic research; naturally, however, this takes time.

See more interviews