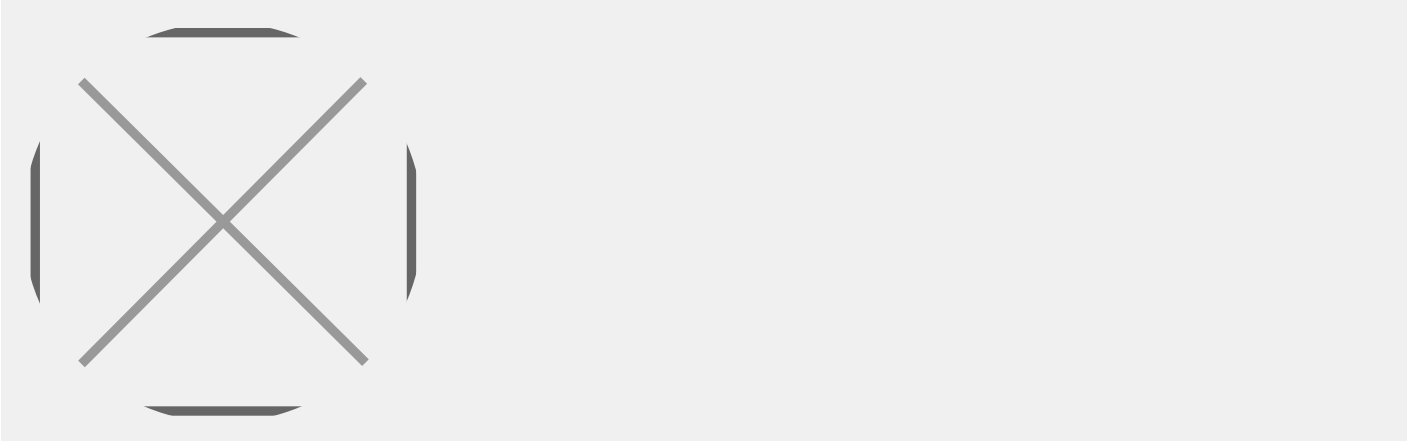
Interview with Laurentiu Mihai, Executive Director, Association of Producers of generic medicines in Romania (APMGR)



30.07.2012

Tags: Association of Producers of generic medicines in Romania (APMGR)

APMGR is obviously a rather young association that has only really been active since about a year now. Can you first comment on the timing that the Association was called into life?

The timing has been quite good, as the generics industry is currently experiencing a strong momentum. Every country, at least in Europe and North America, is experiencing immense demand for medical services and treatment. While the respective products and services come at a high price, public budgets are shrinking at the same time.

The limited budget that needs to be allocated, is required to be used wisely, which inevitably implies the inclusion of generic medicines. Generic medicines give the patients of these countries the opportunity to have better access to healthcare.

The UK or the Netherlands for example have very high generic penetration rates in Europe. In Romania, penetration is still lower at roughly 75% volume and 27% in value. Can you elaborate on the role generics play in Romania, and how you see their presence evolving in the country?

In Romania, there exists a huge opportunity for generic medicines. Of course, Romania is different from other European nations, in particular in terms of the public spend on healthcare. With regards to public expenditure on medical treatment, Romania regrettably holds the last place in the EU. The current expenditure is roughly EUR 70 per person per year, which is a very low figure.

At the same time, the public system is using most of the budget to purchase very expensive drugs. Therefore, a lot of people from the industry have come to believe that an important shift in Romanian public health policy is imminent.

Do you feel that the government now sufficiently realizes the impact that the use of generics can have on the budget?

I think that the Romanian policymakers probably understand this potential at an individual level. However, the legislation that is currently in place is generally insufficient or insufficiently enforced. There are strong marketing efforts that put the Romanian doctors and pharmacists under pressure.

As patients will become more involved in the decision-making on drug expenditure through co-payment schemes, do you think that the current situation may change?

The introduction of co-payment schemes has been a World Bank project in the fight against informal payments. During 2004-2005, I was involved as an expert and external consultant in this area, and also recommended the introduction of such mechanism at that time. Nevertheless, co-payment schemes are only a small part in a much bigger approach. In the US, for example, you may also find co-payment schemes while this has not really been the case within European statutory health insurance schemes. Here, co-payment has not been the main way to ensure wide access to treatment for patients.

Moreover, because of the fact that the prices of medicines are already the lowest in the European Union, Romania has been confronted with parallel trade (of an estimated 15 to 20% of the market). Even if certain low prices have been specifically set for the Romanian market, this is one mechanism that drives these cheap medicines out of the country. Many of APMGR's members have production facilities in Romania, and are henceforth confronted with the lowest possible profit margins. Moreover, as the payback terms for distributors and pharmacists currently amount to more than 300 days, the latter tend to procure higher priced innovative medicines to obtain the necessary cashflow to conduct their day-to-day business. The parallel trade, the low margins and the payback terms are the three mechanisms that drive generic medicines out of the Romanian market.

APMGR's president Damian Dragos indeed recently commented that roughly 1,500 cheap medicines had disappeared from the market, while the uptake of innovative drugs has been rising. How do you see this trend evolving in the future?

This has indeed been the consequence of the 3 mechanisms I have just mentioned. Going forward, there is of course a disparity between what I hope will happen, and what will actually happen in reality. I am afraid that, with the present policies, the actual trend will not be heading in the preferred direction.

At the moment, we feel that all the producers will be affected in a very negative manner by the government's cost-saving measures on fully reimbursed medicines. In fact, it is expected that such measures will be a catalyst for the 3 aforementioned mechanisms, resulting in an increase in parallel exports and negative social effects. Today, all the APMGR members together have roughly 8,000 members in production facilities, and rely heavily on "real exports" as their only real source of revenue. Many of these export destinations today are the USA, Japan, Australia and the UK.

So all these facilities are GMP compliant?

Indeed, otherwise we could not even export to European markets, where we are also present. However, many of the prescribers in Romania do not seem to understand this quality. There are very strong and aggressive marketing efforts in Eastern Europe that are in fact negative propaganda against the use of generic medicines. As long as we can export the current volumes, we can retain a good image abroad. The problem is really situated on the internal market. If you ask a doctor or a pharmacist today, he or she will not recommend the use of a generic medicine, particularly because of the huge delays in payback periods. It is thus only natural for them to sell the most expensive medicines, in order to obtain the biggest amount of cash possible to sustain their activities.

With such huge delays, we cannot even tell exactly how much is really being reimbursed. As the manufacturer sells to the distributor which in turn sells to a pharmacy, it is very hard to tell after 1 year what the payment was for, as this can relate to non-reimbursed, partially reimbursed or fully reimbursed products. This lack of transparency makes it very hard for these companies to have a clear business model.

Last Autumn, it was said that the Romanian generic manufacturers would increase their product launches as the national insurer CNAS was planning a more pro-generic policy. Has this then not been the case?

I have been in constant contact with both CNAS and the Ministry of Health to better understand what the landscape will look like. There is a certain legislation in force, but it is incomplete and not entirely enforced. It is one thing to declare that the use of generics could help the budget, but it is still another thing to adjust reimbursement systems accordingly. At the moment, many original drugs are still entirely reimbursed, which obviously presents an unsustainable scenario.

If we look at the bright side, we have seen many local success stories such as Labormed, Terapia, etc. in the history of the Romanian pharma industry. In your view, what have been the key success factors that made these companies so attractive to be acquired by foreign investors?

First of all, Romania has a strong tradition in the pharmaceutical industry. Terapia had a history of roughly 90 years for example. Naturally, the communist period resulted in a halt to investments in R&D and the upgrading in manufacturing, resulting in certain facilities to become outdated and even obsolete. A second key factor has been excellent management, both by local managers as well as expatriates. The foreign managers have brought a strong set of values, corporate culture and experience, which has been of clear value to Romanian companies.

One important role for APGMR is naturally to maintain strong relations with the government stakeholders. What is going to be your personal priority, having arrived here just one month ago?

The agenda is quite full at the moment, as the changes are occurring very rapidly. We currently do not agree with some of the proposals that have been made by the government, and see the necessity to fight back. Apart from all logistical aspects that I need to take on board now, we strongly need a good communication strategy. We cannot simply complain that some originators have very aggressive marketing strategies. We need to have a meaningful and consistent message about what the generics manufacturers are producing and bringing to the market.

Furthermore, I am determined to increase the visibility on the international, particularly European, markets. Some of our members are already a member of the European Generic medicines Association (EGA), and it is now up to the APMGR to have a say in Brussels and the European Forum.

You have a lot of personal experience at the Ministry of Health too. Do you feel that this has given you a certain advantage in nurturing such relations? And also, why did you initially decide to make the switch from the public to the private sector?

It is probable that this has helped me in better understanding the game and its rules. But considering the framework of public and private sector, I still consider the generic sector as a layer between the government and the innovators. I hope that my understanding of the rules of the game in Romania will help me to seize the opportunity and increase the share of generic drugs in the Romanian pharmaceutical market. As a nation, we can no longer afford to keep spending that much money on innovative drugs at the expense of generic medicines.

Our argument in our discussions with the government is based on the fact that we also recognize the need for innovative companies to be present in the market. Moreover, we believe that the savings that can be generated from the use of generics, can subsequently be used to include new innovative molecules on the reimbursement list.

What role do you see for APMGR in the future?

At a European level, director general of EGA Greg Perry recently shared a growth estimate of 10% for generic medicines in Europe. Here in Romania, we at APMGR are striving to further increase the uptake of generic medicines to match the European growth rate. As I have mentioned before, there is still a lot of room for growth here, and a lot of potential has remained untapped.

Do you have a final message on behalf of APMGR to the readers of Pharmaceutical Executive worldwide?

I would like to address my message to the general public, and reiterate that generic medicines are as good as originator drugs. There are simply not that expensive because they have required far less expenses on R&D.

Do you see the opportunity for the APMGR to increase this awareness and perception of generic medicines amongst the general public?

Definitely. One of our biggest campaigns will indeed be addressed to the general public, and is aimed at enhancing the general awareness of the use and quality of generic medicines in the country. Rather than asking the Ministry of Health to ask for money to invest in such campaigns, my only request is for them not to oppose any such initiatives

See more interviews