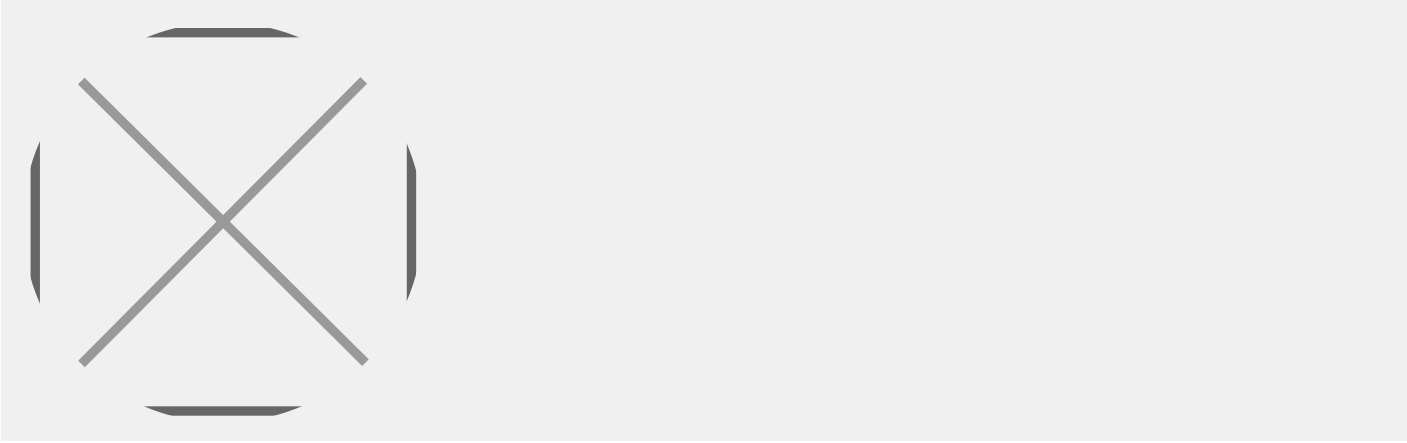
Interview with Dan Zaharescu, Executive Director, Romanian Association of International Drug Manufacturers (ARPIM)



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While, today, you are in charge of voicing the concerns of the innovators in the country, let us first take a step back and see what attracted these companies to Romania in the first place. Can you tell our readers more about the key factors of attraction in that sense?

First of all, Romania is a country with significant growth potential, as the level of expenditure for healthcare in Romania is still very low. This is not only due to the low level of resources of the population, but is also related to the lack of interest or commitment to healthcare from the authorities. The relative share of healthcare expenditure in terms of GDP is 3.6% in Romania, which is far below the average of African and European countries, and matches the level of the poorest nations in the world. The potential for growth is therefore tremendous.

At the same time, Romania is a stable country with over 20 million inhabitants. Moreover, and in line with other trends internationally, Romania's population is ageing. This also leaves room for interesting developments in the healthcare sector, even beyond medicines alone.

Romania has started from a very low level roughly 20 years ago, and has recently experienced tremendous growth levels of 20 to 25% for the pharmaceutical market. However, as from 2008/9, the burden of the financial crisis has made the population more precautious, despite the fact that everyone has been making healthcare a top priority in terms of individual priorities. It should be acknowledged that "Health is Wealth".

When you say that there used to be a lack of interest in healthcare from the government, has this been changing?

In fact, all the political parties in Romania include healthcare policy in their statements. They all say that 6% of the GDP should be the minimum spend on healthcare, which is the minimum for civilized European countries. Yet, in spite of this speech, such levels of expenditure are never allocated once the parties come to power.

Another interesting observation has been that the civil society has mobilized itself to make the policymakers aware of this lacking commitment. There are some patient and industry associations that have started to become more vocal.

The liquidity and payment terms have also been said to be a severe issue for the private sector. Can you elaborate?

The payback period currently amounts to 330 days, or roughly 11 months, and is one of the major threats that the industry is currently facing. Again, the healthcare needs of the population are relatively high compared to the level of resources that are being allocated by the government. So far, the authorities have been able to sustain this lack of funding by artificially extending the payment terms. Officially, these payments terms are 110 days, which means that a debt of 7 months has been consistently created.

Will this improve as Romania further aligns with the EU Directives?

The EU Directive has been published in the official journal of the European Commission in March 2011, and Romania now has 2 years time to transpose that text into its own legislation. After March 2013, there will probably be a period of adaptation for the state and the companies in Romania. Yet, the dramatic reduction from 330 days to the EU requirement of 30 days, will require a huge effort from a cashflow point of view, as well as from the allocation of resources in Romania. This is why, today, ARPIM has been lobbying to pursue a gradual reduction (of 1 month every 6 months) of this payback period. Unfortunately, the opposite is happening today.

Can the privatization of healthcare and the introduction of co-payment schemes offer a way out?

There are indeed some opportunities, but the measures that have been taken in the last 20 years have been too small. Moreover, insurers, active in the healthcare segment, come to Romania to make money. The way the age pyramid of the population is currently evolving is not the most attractive situation for these companies. It is therefore necessary to first have the legal ground to help develop this sector.

Today, there are numerous private medical centers, private hospitals, and so on, but the services that they provide are based on a so-called “abonament”, rather than a private health insurance mechanism. It often forms part of the compensation package that companies offer their staff, which also implies that these kinds of services largely prevail in urban areas and regions with strong economic development. Unfortunately, half of the Romanian population resides in the rural areas, and are therefore limited in terms of healthcare access. From this point of view, the situation is very unbalanced. In turn, this polarization in the Romanian population also offers potential for growth.

If we take a look at the evolution of the local industry, we see –as in many other markets- a clear trend of consolidation, with examples of Terapia and Zentiva being acquired by Ranbaxy (Daiichi Sankyo) and Sanofi respectively. Are we now seeing a different ballgame than 10 years ago?

Over the years, there has been a change in the way the authorities see this sector. Until roughly 10 to 15 years ago, the authorities had dramatically blocked the development of local pharmaceutical companies. Only certain small pharmaceutical companies managed to grow and build their business. At a time when most companies were still state-owned, there was a certain mentality that the state should ensure the social protection and keep pharmaceutical prices at very low levels. These low prices did not give the local manufacturers the required room for developing their production lines, to implement GMP procedures, and so on.

When the foreign investors came to Romania, investments in local facilities increased significantly, which brought huge changes into the management levels, and the way these businesses were run. The many changes that have taken place have benefitted the patients as well as the economy, as the export potential of the industry has also increased over time.

Overall, how would you rate the manufacturing environment in Romania, and which of the innovator firms are engaged in such activities here?

At the moment, GSK (through former Eurofarm), Daiichi Sankyo (through former Terapia) and Sanofi (through Zentiva) manufacture here in the country. We have to acknowledge that the development of new medicines in the pharmaceutical industry requires a lot of financial resources from the R&D side. There are opportunities from this side, if we look at the clinical trials in Romania. Such research can be conducted at small laboratories in Romanian universities and university hospitals. This offers a strong market potential of EUR 200 to 300 million that has not yet been valorised. However, while a trial approval should normally be obtained in 3 months, the current approval term easily amounts to 6 to 9 months. Thus, with some small changes in the legislation, that potential can more easily be tapped into.

Clearly, some changes still need to take place at the government level. What are your current priorities to lobby for at the government?

We have a clear agenda for the short, medium and long term. Unfortunately, Romania currently has no public policy for the healthcare sectors. In the last 20 years alone, the country has seen 20 different Ministries of Health. There is thus a certain discontinuity, as well as a lack of visibility for the longer term. For all past governments, healthcare has not been a priority at all. Today, we are paying the consequences. Even the measures that are being taken today, are disparate measures that are affecting only marginal aspects of the healthcare sector. For the short term, they may solve certain issues, but they do not offer any solutions to chronically ill patients that will gradually become more expensive for the system as a whole.

One obvious achievement for ARPIM has been the implementation of an Ethical Code for your member companies. Was this a milestone for the industry?

It was a big challenge at that time. Still today, the challenge persists as it is only the ARPIM members that respect and follow this Code. We therefore feel that there is a certain discrimination between ARPIM's member companies and other companies that freely operate within the market space. Since the launch of this Code in 2006, we have asked the authorities to implement it as an ethical norm for all the actors and players in this market. Alone we cannot do more than what we have already achieved in this sense.

We are also engaged in ethical guidelines for relationships with Patients Associations, which is also extremely important. In general, the patients are deeply affected by the lacking funding of the healthcare sector. During the preparation process of new guidelines or measures from the government, we therefore conduct an assessment with these associations, to make them aware of the impact that these decisions may have on patients in Romania.

How do you see the Romanian pharma industry evolving in the coming years?

Overall, the pharmaceutical market is inevitably set to grow further. We cannot stop this, as the need for medicines and medical services is so big. This cannot be limited by measures taken by the authorities. While measures such as clawback mechanisms may pose challenges in the short term, the situation will change in the medium and long term. We are of course counting on the fact that the population will have higher revenues on the one hand, but also on the fact that the people of Romania will penalize the politicians for not taking healthcare as a key priority in their policy.

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