Interview with TomaÌ•sÌ? MateÌ?jovskyÌ•, Partner, CMS Cameron McKenna Czech Republic

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CMS Cameron McKenna Czech Republic

Mr. MatÄ?jovskÃ½, letâ??s begin our discussion with a very simple question. The Czech Republic is quite a small country, and yet it seems to have one of the most complicated pharmaceutical regulatory frameworks in Europeâ??ensuring, for instance, that market access for drugs can take up to three years longer in this country than in Austria. As a Czech citizen and as a Czech lawyer, what is your understanding of why this is the case? Is it a matter of culture? Of history?

I believe it is a matter of both. It is firstly very much a matter of history: even before the Second World War, the Czech Republic had a very advanced healthcare systemâ??although of course the specificities of the framework were changed under Communist rule. Nonetheless, the system has traditionally been highly regulated.

After the countryâ??s transition to democracy in 1989, the system remained quite regulated. Naturally, the authorities also tried to institute reformsâ??but this meant that more and more regulations were introduced.

Today, as you rightly mentioned, the system is very complex, and very difficult to navigate. For many peopleâ??even professionals working in the industryâ??it is very difficult to understand.

Because of the complexityâ??we might say the formality, the heavy weightâ??of the system, it has become very expensive. For this reason, the government has now tried to implement a number of changes. I believe that the steps the administration has taken have been positive. However, the reforms are perhaps not radical enough. In my opinion, our healthcare framework needs to undergo more drastic change.

For the changes that we do see, what do you understand as the principal direction of reform, and how is change being manifested in amendments to major legislation such as the Pharmaceuticals Act, Public Health Insurance Act, and the Advertisement Regulation Act?

The principle behind the reform effort is very positive: the authorities want to simplify the system. They want to make it more open. At the same time, they want to retain a proper measure of regulation, because of course regulation is necessary in the healthcare framework and much of the regulation we see comes from E.U. directives.

In terms of drug prices, our government wants to reduce expenses. The consumption of pharmaceuticals has increased dramatically over the last ten yearsâ??which is obviously very beneficial for pharmaceutical companies. We are not yet on the level of a country like France in terms of drug consumption per capita, but we are getting there quite quickly. This has put a major burden on the national budget.

Besides increased consumption, the problem lies in the fact that there is no system of control that dictates who prescribes what to whom. There is no centralized database of patients; this means that if one doctor prescribes a drug to a particular patient, and that patient then visits a different doctor, the latter physician has no record of what was previously prescribed by his colleague. The patients may wind up using cocktails of pharmaceuticals without any necessity for doing so.

Another part of the problem is a lack of transparency in price regulation. In the past, this problem was particularly noticeable; today, the system is much more transparent. However, this change is relatively new, and I remember that five years ago, we faced quite a mess, and the environment allowed much room for corruption. We will see what success the authorities can have with the new drive toward transparency. Steps have been takenâ??but we are by no means finished.

To delve more specifically into some of the concrete legislation you mentioned: the Act on Pharmaceuticals has experienced quite a few amendments this year concerning pricing. There are further amendments in discussion at the parliamentary level. There is major change on the horizon, but I believe that at this point the authorities are not yet quite sure what to implement.

A significant change that we expect to come into law in autumn relates to advertising. Under the proposed legislation, advertising should become much more difficult for pharmaceutical companies. Of course, the current laws governing their advertising practices already make marketing efforts quite difficultâ??but there are today many ways to circumvent the law. I believe that the aim of the new amendment is to prevent this circumvention.

The professionals in the industryâ??particularly those from innovative pharma companiesâ??are quite keen to see the final draft of the advertising law. Life for innovative players in this market is growing more and more difficult, and naturally generic companies are capitalizing upon this fact.

In Russia, your CMS colleague Alessia Akimtseva remarked that while she found that the laws governing pharmaceutical companies were changing for the better, new legislation was often implemented too quickly, and the unpredictability of the environment hindered the work of her clients. Is this a challenge in the Czech market?

Yes, it certainly is. I think that in our market, there is a lot of dialogue ongoing between government and the industryâ??but it is still not enough. It seems that when pharmaceutical companies have some concern about prospective change, their position is not fully taken into account when the final draft is prepared. Even though their comments may have a lot of value, and make logical sense, the officers preparing the law may not accept their arguments, because of their rather rigid thinking regarding how things should be done in this country.

The other problem is that we are still trying to invent the wheel here. The Czech Republic has been hesitant to implement the successful models that we see in other countries. For instance, the Swiss healthcare system works very, very well. It is not overly expensive, but it nonetheless generates a lot of money for pharma players. Instead of adopting models like these, the Czech Republic is trying to go its own way. This is baffling, because our model, as I have said, is very expensiveâ??and it does not work very well.

One of the problems that members of the industry commented upon in Russia was that the officers charged with developing reformatory legislation were career bureaucrats with little practical experience within the pharmaceutical industry.

We see this problem in the Czech Republic as well. If we look at the people within the Ministry of Health, although they are becoming more sophisticated in their approach, they are still limited in their understanding of the pharmaceutical industryâ??or for that matter, the healthcare industry: for instance, the challenges faced by hospitals. If our officials do not have a proper understanding of these two components, which are at the core of the healthcare framework, then the system cannot succeed.

To reach a better understanding, more dialogue is necessary. The major portion of dialogue occurs between the Ministry of Health and the health insurance companies. However, the insurance companies are motivated by the generation of revenue and the containment of costs. At the same time, healthcare is getting more expensive, and our population is agingâ??which means that costs should only rise. We need to spend more, not less. Nonetheless, we are indeed spending less: I read only last week that out of all OECD countries, we are one of only two where expenditure on healthcare is decreasing. Income from health insurance has been at a lower level than in the past, so the system is generating less money; and, although the government is trying to spend less, they are actually not doing soâ??they are spending less on matters of importance, and more on less important elements like administration.

In our discussion with Mr. DvoÅ?Ã¡Ä•ek of the innovatorsâ?? association AIFP, he noted that he sees a lack of fairness and balance in the systemâ??when cuts are made, it seems that pharmaceutical companies are always affected first. Do you expect this scenario to change, with the implementation of measures like Health Technology Assessment?

It should. From the discussions that we at CMS have had with the Minister of Health, Mr. Heger, this is the Ministryâ??s aim. But I am not sure yet how these ambitions will play out in reality.

Letâ??s consider, for instance, the E-Health initiative, which should in theory generate a good amount of money even for pharma companies, while making the system as a whole less expensive. In Hungary, E-Health has already been implemented, and the country is quite progressive in this sense. Here, the conversation about E-Health is only in its beginnings.

In some respects, we are well ahead of neighboring countries like Hungary; in other respects, we are very much behind.

An interesting point that has emerged from many of our interviews is that while the level of healthcare itself in the Czech Republic reaches Western European standards, the legislative system is quite a bit behind. How do you explain this dichotomy?

I think that any time a politician wanted to affect true reform in the healthcare system, their efforts were largely squashed. Healthcare has always been a political issue. The coalition governments were never strong enough to push change through. Our current government was â??strong enoughâ?? for a while, but it has now lost a number of MPs and hence we will see how the situation plays out.

Healthcare must be de-politicized for true reform to come to the system. But this hasnâ??t happened yet.

Ultimately, what advice is CMS giving its pharmaceutical clients about the market? Is it attractive to invest in the Czech Republic?

I think that despite the problems, the market is attractive. There is a good amount of capital in the system, and, although we would like to see it function better, it is functional nonetheless.

The Czech Republic, therefore, is interesting for investors, pharma companies, and manufacturers of medical devices. It is very much interesting for clinical trials, as wellâ??this industry has been booming here in the last two or three years.

Letâ??s look more closely at the positioning of CMS as a service provider to the industry. One of this firmâ??s great advantages is that it has an industry-focused practice. However, many large law firms, such as Baker & McKenzie, have also aligned their work around specific sectors. What else sets CMS apart?

We have been on the market for the last 21 years, and we are one of the first international law firms that came to the Czech Republic. We are also one of the first law firms to create sector groupsâ??life sciences being one of them. While we are not the only law firm to focus our practice in this way, we were a forerunner.

Today, I believe we have a good knowledge base, and a good client base. Our position in the market is very strong. It is very difficult to measure the market position of a law firm, but our business is stable and we consistently gain new clients without suffering very much client loss. I am proud of the fact that, even in this difficult economic climate, we rarely lose clients to local firms that offer cheaper services than our own. This is a sign that we are doing good work.

What proportion of your business is represented by life sciences?

It is certainly not the major proportion, but I would say it generates about 15% of our revenues. Within five years, I hope that we can represent at least a quarter of this firmâ??s income. The strengths of the life sciences sector groupâ??not only in the Czech Republic but also in the CEE region and within the firm as a wholeâ??are immense. There is still potential for us to grow.

What changes do you expect the industry to undergo over this same five-year period, and what opportunities will these changes create for lawyers?

I think that for the pharmaceutical industry, the battle between generic and innovative companies will really come to a head in the coming years, and I believe that as a result, many generic players will be acquired by innovators. This is perhaps the only way to proceed, because generics are becoming increasingly stronger. This makes sense: generics are cheaper, and governments worldwide are turning to this sector as a way out of their budgetary challengesâ??which is not a positive trend, because innovative companies need large amount of income to continue to make advances in R&D. I believe that innovators will therefore increasingly broaden their revenue base with the integration of generic arms. We see that for many companies, this has already happened.

In the Czech Republic, the environment will also continue to see the implementation of new laws. It is certainly an interesting time for lawyers. Nothing is stable: down to the changing trends in the courts, and the litigation regarding patents disputes, etc. The whole life sciences industry is very much alive!

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