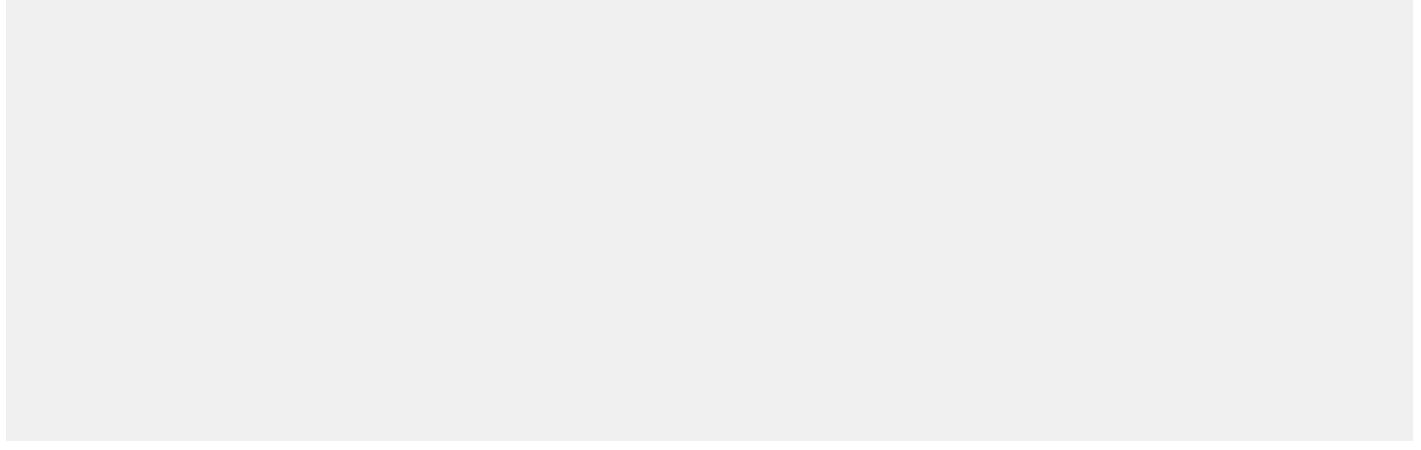


Interview with Jan Kotek, Executive Director, Sdružení výrobců volně prodejných léčivých přípravků (SVOPL-OTC)



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Mr. Kotek, can you please begin by introducing us to the SVOPL and telling us what the mission is here in the Czech Republic?

We are a relatively new Association that was founded only back in 2000. Before, we were a branch of a larger Association of international drug producers (now AIFP).

The purpose of our Association, SVOPL, is threefold. First, we want to align the interests of public and health care systems and professionals. Secondly, offer a sufficiently broad range of OTC medicines to public and physicians and to help with the treatment of normal (acute) illnesses or contribute to a healthier way of life. Lastly, we would like to set a ground for and apply the principles of self-medication practices in Czech Republic.

As a contribution to achieving this goal, all SVOPL members are committed to the promotion of prescription drugs to comply with the principles contained in the Code of Ethics. Acceptance and compliance with the Code of Ethics is a condition of membership in SVOPL. The non-members are welcome to join SVOPL and adopt and enforce this Code.

In addition, nowadays, we have a lot of problems with different opinions as to our activities.

What would you say are the obstacles your members are facing today?

For example, many of them touch on the changes that begin on July 1st 2012. The new reform will cancel any reimbursement, even a partial one, of any OTC drugs. This will have an impact on patients, distribution, health professionals and manufacturers. As described so far, this can lead to a chaotic situation where the prices of these products are unknown.

Unfortunately, I see it as a negative development. Our specialists, the Ministry of Health and, in particular, the Parliament decided on the additional and substantial changes without further discussion with experts or with us. It is quite obvious that they do not understand the nature and advantages of OTC drugs – safe, proven and effective drugs which are drugs of first choice for the majority of the population of this country. Patients will not be happy because they will probably have to pay more money than before. It's hard to explain the whole process that seems to me to be very unfortunate and illogical.

You can see that the state tries to save money but, in my opinion, it does not make it across the board. Other problems are the lack of public education about the benefits of self-medication and a proactive approach to their own health. This lack of education is also related to pharmacovigilance issues, we need a lot of money and time to educate patients because they do not know what side effects are and what to do if they develop them.

In most developed countries of Europe, the use of OTC medicines and active support for self-treatment is part of the public health policy of the state. We try to explain to the public but also to the authorities that self-treatment has great potential for savings and for improvement of general health. It seems as if they were too occupied with discussing only the most serious diseases that they cannot see the role of OTC drugs in the treatment of a wide range of both common diseases or in preventing the most basic health problems that, with time, can develop into a more serious disease.

Other current problem is the benevolent market access control our authorities have towards advertising various non-drug products which are presented as a cure or prevention for a variety of specific health problems. This perhaps will come to an end with the European Food Safety Authority regulation, EFSA's regulation. We would like to change the fact that pharmacies currently sell all kinds of products (non-drugs) together with drugs (medications). Most pharmacies have filled their space with non-drug products, even shoes, and the patient does not know what is a medicine intended for treatment and what is a non-drug food supplements or cosmetics.

They have no chance to see pharmacies offer OTC drugs for their treatment. We need to spend a lot of time explaining to the public that OTC drugs are here for their good health and prevention,

and that food supplements or cosmetics cannot replace them in the treatment chain. For better sales and patient orientation on the market, it is very important to make this drug – non-drug division more visible in pharmacies.

Because the products will no longer be reimbursed, they will no longer be regulated. Why are these things connected?

It is an emblematic example of our legislation. The changes that began more than 20 years ago, the rapid growth of new products, and the government stated that in every therapeutic group (even for OTC drugs) must be at least one drug fully compensated by the State Health Insurance Company. More products also used the partial reimbursement scheme as paid drugs were under state regulation.

This directly relates to price, distribution and other regulations. In the regulated final price was a calculation of exact coefficient for distribution. Everybody had access to this information and could see a list of drug prices. Now, without regulation the prices can jump, for example, higher than for not regulated distribution margin. People will start looking for price information of non-regulated drugs.

Is not this similar to other European countries where OTC products are usually not reimbursed?

OTC products are OTC because they are very safe, effective, so people can buy them and do not need to consult a physician. But there are also OTC drugs that are intended for the treatment and prevention of acute and long-term illnesses and other serious health problems such as allergies, atopic eczema, and problems related to blood circulation or musculoskeletal problems. All other European countries reimburse some OTC products for these conditions. I hope we will very soon come to a similar conclusion based on specific health indications. Otherwise, the elderly or young families will not have enough money to afford these treatments.

We will have to explain to physicians and the public that it is not the result of our efforts to stop their protection or increase the prices. Secondly, we need to explain that the OTC drugs are effective, safe and cheaper than other products in pharmacies. Also, they can be a powerful tool even for Czech economy of treatment together with generic drugs. It will surely impact the switch from RX to OTC products. It is also possible that some products will be forced to withdraw from our small market. And where does the patient stand?

How do you think your members will respond to this change and how will it affect their business?

Our members have very different ranges of products and services, depending on which products are important for them to address their corporate strategy. For some of them it will be same as before. Surely, it will affect the fact that all OTC drugs not covered by insurance will not be regulated. It is quite a new situation for our market and we will be able to evaluate this situation later.

Are your members, for instance, selling food supplements labelled as drugs?

More of our members are also manufacturers of food supplements and other similar products. As international producers they have high quality products and products procedures, they are using very strict rules for their production, distribution and for advertisement. After the introduction of the effectiveness of EFSA, prohibiting certain advertising claims, I predict a slight and short decline in sales of this class of products, especially with smaller producers.

On the one hand, we do not know what will happen to prices and on the other hand, one of the channels for their sales growth will be now closed.

A report by the Business Monitor International, a research group, says that the OTC market will grow by 13% between now and 2015. Do you disagree with this figure?

I am quite skeptical. It will probably grow faster than the RX, but it will not be as high as 13%.

Tell us what is driving the sector? If the population is not growing, something else needs to grow.

That is a good question. The population in our country has not growing since last couple of years. It is actually aging dramatically, extending the retirement age. I think we need to introduce and promote a healthier diet and try to change a way of life of our population. What we need is a more active approach to our own health and life, regular exercise, more time for our friends and families. Not so much negativity flowing from the media and so much bureaucracy. What we need to find it very soon in better health strategy and health policy, for patients also implement combination of health and social care, which is very divided nowadays. Every delay in this area is prolonging our Health and Social problems in future.

Do you expect your members to be able to raise their prices or will it be the pharmacies that will increase the prices?

Most of our members are large and long established companies. They will try to remain at the same price level and try to maintain the distribution of sales, which will have a free margin beyond our control. The price level is only one of the attributes that are crucial for our members. As the

time goes, we will see if these measures were good for us, if the purchasing power of citizens and the state was sufficient to support the role of prescription drugs throughout the health system and to support public education. With the lack of active approach of our population to their own health, we are seeing an increase in serious civilization diseases, the follow-up treatment is very expensive and long term but what is important is that their origin is mostly preventable with principles and applications of self-medication and OTC drugs.

Mr Kotek, how would you describe the relationship between producers and pharmacies in Czech Republic?

In general, it is good. There are slight differences between us and pharmacies concerning the implementation of advertising and consulting but this is not a major problem.

Most pharmacies are trying to earn as much as they can. We are working hard with them to find common ways to help the sick. This cooperation, however, might be influenced by the upcoming changes in legislation. It is possible that some of our members will have no reason to continue visiting GPs and informing them about the situation in the market and offering their products. In turn, the GPs might not know what is best to prescribe or recommend to patients.

Mr Dvořáček of AIFP, for example, does not think this law will pass. What is your relationship with the government? Do you have a strong voice?

No, we do not have a very strong voice because we have fewer members than AIFP and other associations. In terms of OTC drugs, we are not backed by such famous leading hospital specialist whose views are well respected. Our issue area is related to the daily care of wide variety of health problems, it is mostly linked with pharmacists and GPs who often have their own interests. That is why the OTC debate seems to be invisible. Health officials in Czech Republic are too occupied with serious diseases and expensive treatments in big hospitals, even though it concerns only a minority of Czech patients. Therefore, we do not cooperate as much as it would be needed.

Imagine a pyramid, where only a narrow tip on the top consists of serious illness and is covered by health care of hospitals and their specialist physicians. All the rest of the pyramid, about 85%, is made of common diseases and long- term illnesses which patients treated themselves at home, although some of them with medical instructions. This area, however, remains hidden from the Ministry of Health and health specialists.

What is your estimate on the percentage of the market made by OTC products?

I am sorry as there are some changes I have no exact figures to share here. It is about 30%. OTC drugs are very safe and effective even for longer-term use, they should be the drugs of first choice and due to these features they should be supported by the Ministry Health and used as much as possible.

Our government does not pay any attention to this fact and all health-related laws are prepared and edited only with focus on not so safe (mostly new) Rx medicines. It is often driven by hospital experts, a small group at the top of the pyramid. I am sure that it will change once.

What about your members such as GlaxoSmithKline or Pfizer where OTC is only one part of their business? How focused are they on the OTC market in Czech Republic?

Such bigger companies offer their non-prescription medicines only as a minor portion of their total offer. They have specific organizations and are usually managed indirectly from their mother company and do their best to be successful also in our small market. Many changes in this sector are also results of more M&A focused on main company products and their relationship usually regardless on OTC products. We can see it also on changes in OTC staff, business policy or strategy changes. The role of the bodies representing these companies in the market for OTC drugs is often different.

In particular, we must focus on our members' communication and strategies and cooperate with pharmacies, general practitioners and the public to support advantages of OTC drugs and their correct role and application.

So you need to speak to pharmacists.

Do you know how it works inside a pharmacy? Most of OTC drugs are issued by young girls who do not care that much about what information they give to the patient. It is a pity because that is where the patient needs an experienced pharmacist to provide an advice and learn how to properly use such medication. We are trying to find a common approach and improve the situation. For us, same as for the public, it is vital to provide enough information and variety of products for better treatment.

What kind of advertising measures reach the Czech patients? How do your members inform the public about their products?

It is a question of money. Each pharmaceutical company focuses on a few profit-making products and other products are just a complement to their total offer. The selected products are then the subjects of advertising and marketing activities. Most effective and most expensive is television

advertising, of course, for more detailed information it may be internet and PR material. It depends on the preferred strategy. It is a question of preference, whether they want to promote the brand with its name and plant identification or do they want to promote specific benefits of the selected product.

What is the attitude of general public towards self-medication? In Russia, for example, people are self-medicated and try to treat things with alternative treatments and, generally, do not like to see doctors.

It depends on your perspective. I would say that it is similar to Russia in this regard. In fact, there are two large groups of customers who are genuinely interested in self-medication; mothers and seniors. For others, it depends what health problems they have. Some patients go directly to see a doctor or some go ahead and start their own treatment and within a week if the treatment does not work they visit a doctor.

In our opinion, everyone should first try self-medication for about six days. Often, when people come to the hospital or GP immediately, they run all tests, order lab work, x-rays, which cost a lot of money and time while, often, there is no diagnosis because it is too early to perform all these tests. In the Czech Republic, unfortunately, nobody supports visibly our view.

We usually use these reports to provide a platform for a dialogue among different stakeholders, ministers, innovators and generic companies. In this vein, it is a great opportunity to voice your concerns. Can you give us some concrete steps that the SVOPL is taking or will be taking in the next one or two years regarding the OTC perception problem?

We are preparing several seminars for health professionals and members of the Health Committee of Parliament on what OTC is and why it is good. We would like to get back a partial or full reimbursement for the selected OTC drugs in specified health indications and long-term illnesses.

In addition, we are in the process of preparing a series of PR articles for the general public to explain that it is not our aim to raise prices but to offer them high-quality, effective and inexpensive products on which they can rely.

Finally, we will seek to influence the Ministry of Health and SUKL (State Institute for Drug Control) to help educate the public on self-medication and active prevention. I hope that one day we will reach real consensus and cooperation.

A personal question. Your job has a lot of challenges, why did you decide to become a head of the SVOPL?

Many years ago, I contributed to the provision of education to doctors about treatment of smoking and prevention of smoking related diseases. This topic was very familiar to me, it is similar like self-treatment in our conditions, so I thought that I could take this job and start with a similar focus area.

At the beginning of the project on smoking-related diseases, I talked to one professor, a doctor, who laughed at me when I said that smoking is a disease. This is really a disease as smokers are like user of drugs. When they do not smoke, they get withdrawal symptoms caused by lack of nicotine in the blood. Smoking is also associated with about fifty other diseases such as cancer, and affects your overall health. I just wanted health specialists to support treatment of smoking as soon as possible. OTC smoking-related medication is available now after longer time slightly supported so I guess it was in our conditions success.

What would you like your final message to be to our readers?

I believe it will get better here. We have to spend a lot of time, patience and money on training people and health professionals in active self-medication and use of OTC. They only have very limited knowledge on this subject which is not good. Often we hear from them that they do not need to discuss issues related to OTC because it is simple but, in practice, that does not mean that people understand it. In Great Britain or France, there is a history of studies on smoking or many on lifestyle diseases such as diabetes, high cholesterol or obesity. These studies then set the recommendations for general public on self-medication and healthy lifestyle. I believe that this will soon be the case even in Czech Republic.

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