Interview with Pavel BÅ?ezovskÃ½, Director, State Institute for Drug Control (SUKL)

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State Institute for Drug Control (SUKL)

Mr. BÅ?ezovkÃ½, can you begin with an introduction to SUKL and its role within the Czech Republicâ??s complex regulatory environment?

I would like to begin by noting that I have been at my position as director of SUKL from the 1st of May of this yearâ??today, I have been six weeks on the job. However, I was previously the chairman of the Categorization Commission at the Ministry of Health from 2004-2006, and we prepared the transparency directive related to prices and reimbursement.

All inherent procedures were very well described in this directive. The first subsequent step was to set up an organizationâ??SUKLâ??that would be able to build upon the actions of the Categorization Commission, and operate independently from the state, while receiving supervision from the Ministry of Health.

SUKL is the Czech equivalent of the FDA. We oversee drug registration, maximum price, and reimbursement. Additionally, we control the operations of pharmacies and distributors. I hope that history will find that we have done our task well.

The last years have been marked by a number of overhauls in the Czech healthcare system, affecting areas like pharmaceutical pricing, market access, and drug marketing. Can you give our readers an overview of the main changes in the system, and remark on the overall direction of the governmentâ??s reform strategy?

Firstly, we seek to abide by the directives that are handed down from the European Union. We recently implemented, for instance, a statue about vigilance in our drug code, delineating our response to drug falsification.

Another new law coming on the books, following its adoption elsewhere in Europe, is on the use of medical marijuanaâ??something we will likely base on the Netherlands model, with the drug distributed by the state for special diagnoses.

In addition to heeding the lead of the E.U., one of our main drives at the moment is to cut administrative resources and better manage the state budget. Our insurance system is based on many payersâ??both employers and employees. In the Czech Republic, the population is aging, and consequently, we need to allocate more capital to the care of elderly people. This age group tends to use a greater number of drugs, and is growing at a rate of 3-5% per annum. Compared to other countries, I find that we have the challenge of an aging population under controlâ??although I cannot

say for how long.

There are always new problems, with things like biologic therapy, gene therapy, and other advanced therapies coming to the market. We must compare the outputs from studies conducted on these drugs in other markets, to ensure that the most useful and economically viable therapies reach the population.

How are your efforts with areas like health technology assessment (HTA) creating a more â??fair and balancedâ?? budget?

This question goes beyond the national level. We must think in a more sophisticated fashion, and align ourselves with similar economies. From this point of view, we find Scottish guidelines quite useful. Their framework for HTA is progressive and economical. We are trying to model our system after their own.

On the point of â??fair and balanced,â?? we are not in heaven, and we cannot satisfy all budget concerns. However, we are improving the system. For instance, medical devices do not currently receive enough regulation and oversight. We aim to apply the same structure for registration, life cycle, and reimbursement to medical devices as we have for drugs.

A 2011 study by the IMS revealed that 93% of drugs on the Czech market are introduced up to three years later than in neighboring countries like Austria, Poland, Hungary, and Slovakia. Are the market entry barriers in the Czech Republic too high?

This question is a matter of registration and use, and reimbursement. We can register the drug, but we must secure a special agreementâ??a willingness to payâ??for each product.

Our procedures, following from the stipulations of the transparency directive, are extremely complex, and we must follow them precisely. If companies do not provide us with a comprehensive set of clear materials, then delays occur. It is due to the complexity of the system that the registration period in this country is so lengthy.

The legislation to reduce this complexity should first come down from the Ministry of Health. With that said, we as SUKL are working with the Ministry to make shortened registration times a reality.

Members of the industry have expressed concern that the referential drug pricing mechanism in the Czech Republic, ensuring some of the lowest prices in Europe, is leading to the parallel export of up to 22% of certain categories of drugsâ??causing a shortage on the market. How is SUKL addressing this issue?

The prices in the drug market are those that we can manage given our current healthcare budgetâ??we must be able to afford new drugs, and drugs for special cases, and etc. Furthermore, from a patient point of view, low prices are a great benefit.

However, as the E.U. is a free market, we cannot stop the flow of free trade, and we cannot regulate export. What we can do as SUKL is to control the distributors and pharmacies. We are working on a requisite that will consider distributors and pharmacies as a single provider, and ensure that distributors can only distribute drugs to their particular pharmacies.

We have data from both sidesâ??pharmacies and distributorsâ??and monthly, we receive figures regarding the flow of drugs in the system. Hence, we can keep a good eye on the market and respond to shortages.

Do you believe that the reforms coming to the healthcare system are creating a more attractive environment for pharmaceutical companies?

My goal is to be more proactive with the registration of drugs. New drugs can change treatment paradigms and change the approach that doctors take to treatment and diagnosis. Outcomes can become more economically viable or effective for patients. Hence: my first goal is to shorten the registration period. The industry will too benefit a great deal from this.

To what extent are you working with the industry as partners? Industry associations have commented on the increasing openness at the Ministry of Health. Will this be a hallmark of SUKL as well, under your leadership?

Yes, it will be. I plan to meet regularly with the directors of the associations, as well as representatives from companies. We must all work together to agree on prospective legislation, such as the coming directive on drug vigilance. I hope the industry will find us to be open.

What is SUKLâ??s vision for the next five years of Czech healthcare?

We have already discussed our drive to shorten registration time, and to regulate medical devices.

Additionally, we will inject more technology into the healthcare system. For instance, we are developing â??e-healthâ?? activities, and 2000 pharmacies have already joined the initiative. We also just had a discussion with the Ministry about instituting electronic identification cards. The broadening of HTA, too, is a priority.

I have mentioned to all organizations working in the industry that we are now much more open to discussion and to change. Discussion is necessary; change will affect a better healthcare system for our citizens and our businesses. We know that changes cannot, moreover, be a surprise for our stakeholders; the pharmaceutical industry needs predictability.

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