Interview: ZdenÄ?k Blahuta â?? Director, State Institute for Drug Control (SUKL), Czech Republic

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The Director of the State Institute for Drug Control in the Czech Republic highlights the Czech pharmaceutical industry as emancipated and points out their tremendous contribution to employment, export balance, the economy at large and to the patients.

You assumed the position as interim director of the State Institute for Drug Control (SUKL) in February 2014 and were recently officially named director. What are your current priorities in order to ensure quality healthcare to the Czech population?

The primary task of the State Institute for Drug Control (SÃ?KL), and hence also a task of mine, is to safeguard high-quality, effective and safe pharmaceuticals for Czech patients. Therefore, all of my efforts in my current position are aimed at this primary objective.

As an example of one of the most current topics, I can mention the preparation of the system of mandatory electronic prescription and associated process of modernization and comfort enhancement within the entire system for all key stakeholders, i.e. patients and healthcare professionals. These activities focus upon a flawless provision of electronic prescription in the coming period when the number of users and hence the number of issued electronic prescriptions is expected to grow with the approaching timeline for mandatory electronic prescription. Furthermore, we are currently preparing new activities and measures in relation to the restriction of re-export of

pharmaceuticals outside the Czech Republic which is to be covered by the amended Act on Pharmaceuticals.

The EU is currently discussing the implementation of an export waiver under the supplementary protection certificates (SPC) scheme. Generics account for two thirds of the volume of drugs in the Czech market; bearing this in mind, how do you think this directive, if it comes into legislation, would impact the availability of drugs at the current price level in the Czech market?

At the moment I donÂ´t dare estimate how and to what extent it might specifically influence the Czech market. Nevertheless, I think this is a step which may have a positive impact in respect of quality and availability of medicines also for Czech patients.

Is it a challenge to follow EU directives whilst ensuring safe and high quality care in the Czech Republic?

I am certain that the basic principle of all EU legislative documents in this area is the effort to ensure safe and high-quality medicines for patients across all Member States under equally applied conditions within individual countries. Our obligation is then to fully respect any legal regulations, no matter whether they originated on the national level or whether they were implemented.

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The price reference system in the Czech Republic leads to some of the lowest prices for pharmaceuticals in Europe, limiting the attractiveness of the market. However, market access is seen to be one of the most efficient in the region. How do you assess the attractiveness of the Czech rules and regulations for pharmaceutical companies, which provide the treatments and drugs to Czech patients?

All I can say in this respect is that the rules for the pricing are firmly set forth by the Act on Public Health Insurance and SÃ?KL is not only authorized, but also bound to observe the law.

Despite being a relatively small market and, moreover, a country which has one of the cheapest medicines in the EU, the provision of access to medicinal products is of a very good standard here â?? at present, more than 8,200 medicinal product presentations are traded on the Czech market.

New regulations put in place will limit the re-exporting of pharmaceutical products by mid-2016. Some of our interviewees are of the opinion that the new legislation does not limit re-exporting enough, whilst others argue that the new legislation is a challenge to the industry. What is your position on the new legislation on re-exports?

I believe that the purpose is not to completely stop parallel trade with medicines. It is a qualified, targeted and effective measure with the task being to identify the need for intervention in situations when a conflict of the right for free movement of pharmaceuticals and the public interest â?? i.e. the interest of Czech patients to gain access to medicinal products intended primarily for them when needed â?? arises. SÃ?KLÂ´s role will be the collection and evaluation of data about the movement of medicinal products within the country and to foreign countries and preparation of a draft list of â??jeopardized medicinal productsâ?• for the Czech Ministry of Health â?? these are products which are irreplaceable and whose export abroad would mean limited access to the concerned treatment for the patients.

As the FDA equivalent of the Czech Republic, to what extent do you see the pharmaceutical industry as partners?

The relationship between SÃ?KL, as a state regulatory authority, and pharmaceutical companies as regulated entities, is clearly defined by legal regulations. Of course, predictability, transparency, and outgoing approach within the decision-making practice of the Institute should be a natural parameter of this relationship.

What is the role you foresee for the pharmaceutical industry for the benefit of the Czech population?

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The pharmaceutical sector in the Czech Republic is much emancipated and within the scope of legal options has been looking for ways to its successful operation in addition to the manufacturing of medicinal products. As an example, let me mention the activities of the Association of Innovative Pharmaceutical Industry which implements a number of projects from a free on-line advisory for patients to activities related to transparent cooperation between professionals and pharmaceutical companies. I think this is a very good way for possible future development in this area. I should also mention the role of the pharmaceutical sector in terms of positive development of employment rates, export balance of the Czech economy, the technological standard or benefits of clinical trials for healthcare professionals and, primarily, for patients.

The ministry of Health issued the national strategy on Health 2020 at the beginning of 2014. How do you assess the potential this has to improve the overall health of the Czech population?

The strategy reflects the intended actions and development of public health in the Czech Republic. Furthermore, it includes also the implementation of the WHO Health 2020 program. The primary objective of the strategy is, in particular, the implementation of mechanisms for the improvement of health and quality of life of Czech citizens in a long-term perspective. I believe the strategy covers all current and potential future issues in this area and the fulfilment of the objectives it has set, will have a positive impact upon the Czech population.

As the Director of the most important institution within the healthcare sphere of the Czech Republic, what is your dream for Czech Healthcare in the future and what will you have realized in the next five years?

My wishâ??and I will do my best to achieve itâ??is for SÃ?KL to remain an independent and respected medicines agency which is capable of fulfilling its tasks on a highly professional level. The objective I have voiced also includes an even stronger position of SÃ?KL within the EU Regulatory Network. I believe that even today SÃ?KL ranges among the top players in the performance of regulatory competences within the countries of Central and Eastern Europe.

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