Interview: Martin MÃ¡tl â?? Executive Director, CAFF, Czech Republic

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The executive director of the Ä?eskÃ¡ asociace farmaceutickÃ½ch firem, the Czech Republicâ??s generic pharmaceutical association, elaborates on the code of ethics recently implemented and followed by all its members, which exceed the standards set in current legislation. Furthermore, he explains the implications for the industry of the ongoing EU-level discussions surrounding the supplementary protection certificates scheme.

You were appointed executive director of the CAFF eight months ago. What have been your main priorities since?

First and foremost, I was focusing on fully implementing and amending the guidelines of our ethical code of conduct. The code is a vital part of the certification process of pharmaceutical representatives. All of our members were obliged to implement the ethical code of conduct within their operations and certify all of their employees who are in contact with medical professionals before the end of 2015. Furthermore, I concentrated on continuing my predecessorsâ?? activities, including significant efforts to change the public insurance law in the context of medical pricing and reimbursement.

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In a recent interview, you were quoted as saying that the standard of the code of ethics the CAFF has established is higher than the standards required by the current legislation. In

which sense does the code of ethics implemented by you have a higher standard than current legislation?

The ethical code of conduct is a tool for self-regulation in a sense the legislation could not ensure. Our intention has never been to simply follow the guidelines issued by the relevant regulatory authorities, as some aspects, within the advertisement regulation for instance, are substantially different of the quality of ethics we aim for. Whatâ??s more, if the regulatory authorities were to change legislation in order to implement industry-wide higher ethical standards, the results are rather unpredictable. By implementing our own ethical code of conduct in parallel to ruling regulations, it ensures a higher standard of ethical conduct whilst ensuring that the safety of the patients is not impaired.

What are the current legislative hot topics for your members?

On an EU level, there is currently a discussion surrounding an intellectual property protection waiver under the supplementary protection certificateâ??s (SPC) scheme. This activity is coordinated by the Medicines for Europe organization. Under current law, the patent of an innovative pharmaceutical ingredient can be extended by the amount of time it takes to go through regulatory authorities to gain market access. There is, however, one effect that is not taken into account in the current debate: the SPC is only valid in the EU area and not on markets outside of the EU, which means a significant disadvantage for pharmaceutical companies manufacturing within the EU as we cannot compete with markets outside of the EU. Currently, the Medicines for Europe organization hand in hand with the European commission is trying to amend a law that will allow exceptions to the SPC thus allowing EU companies to export their products to non EU markets which will stop the need for the full transfer of the manufacturing process to non EU countries. This point has also been included in the EU single market strategy.

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On the domestic level, the regulatory authorities are currently debating the adaption of existing EU directives regarding clinical evaluation, in addition to coming limitations on re-exporting activities. Another of our key priorities is the implementation of measures regarding the EU falsified medicines directive and the related delegated acts. We are currently negotiating the establishment of the national medicines verification organization to fulfill the requirements of delegated act. The role of the organization is the selection of service provider, and financing and overseeing the operation of national medicines verification system; the system must be fully operational by February 2019.

In January this year, you initiated a survey in partnership with IMS health, on the use and perception of Biosimilars among Czech practitioners. What was the rationale behind initiating this survey?

The topic of biosimilars had already arisen within our group of members in 2015, hence why we set up a roundtable to discuss concerns and opportunities. It became clear, that there were unanswered questions regarding the consumption of biosimilars as well as the general perception of biosimilars from a medical professional standpoint. Our aim therefore was, to shed light to these questions and analyze current consumption and medical practitionerâ??s perception of biosimilars in the Czech Republic. The survey in collaboration with IMS health was a mere aspect surrounding our efforts to elaborate the topic of biosimilars for our members.

What else did you do to elaborate on the significance and future outlook of Biosimilars?

We were able to attract professor Cornes, a UK based oncologist and advocate of biosimilars and its potential for the benefit of patients, to come to Prague and speak with our members. Included in

this dialogue were medical practitioners whom had the opportunity to communicate their experience, concerns and opinions surrounding biosimilars. To gain the perspective of the complete health ecosystem, we additionally invited representatives from the health insurance companies as well as leading lawyers in the field of health to join. Overall, I believe we were able to address and eradicate the concerns surrounding biosimilars for our members and a large proportion of medical practitioners in the Czech Repuiblic.

The overall result of our roundtable discussion was that the main benefit of introducing biosimilars to the Czech market is the unmatched benefit for patients! Biosimilars are a non-replaceable representation of biological medical treatments available to a wide range of patients and furthermore enable medical practitioners to treat their patients with quality care much sooner than possible at this moment.

Upon assuming the position as executive director of CAFF, you said you would strive for a balance between the regulated market and a stable, predictable market environment. What is the right balance for you and your members?

This is best explained using an example. As mentioned before, one of our intentions is to change the public health insurance law in the area of pricing and reimbursement. We are currently in the process of achieving that prices and reimbursement of medical preparations will be determined according to medical preparations already registered and available on the Czech market. This procedure would represent international standards and the right balance between the market environment being regulated whilst stable and predictable. Unfortunately, the domestic regulations currently allow, that in some cases it can happen that preparations are referenced to medical preparations not available on the market.

Generics are an affordable solution for replacing innovative treatments; thus helping an economy to tremendously save money and allow more patients access to quality treatments. Just how attractive is the Czech market for generics and what is the role they play in Czech healthcare?

Overall, the Czech Republic has a significant history with the generics industry and is traditionally one of the most significant generic markets in the regionâ??in numbers that translates into two thirds of market share in volume and one third of the market share in value is generated through generics.

Before 2012, market access and making it on the reimbursement list was very difficult for new preparations as there was no distinction made by the regulatory authorities between the original innovative pharmaceutical and the generic pharmaceutical. This led to significant time delays between registration, market access and being on the reimbursement list. My predecessor was successful in convincing the relevant regulatory authorities to change legislation in order to have an appropriate differentiation between original and generic, thus allowing the mechanism we have in place todayâ??which guarantees being on the reimbursement list within two months of market registration.

The dialogue between public and private entities is a significant aspect of attractiveness for the healthcare industry, how would you assess this dialogue in the Czech Republic?

Frankly speaking, the dialogue exists but it is not the most effective. The authorities listen to our concerns and consider our opinions. However, on the state institution level several of the industrial concerns and opinions meet and more often than not contradict each other. Unfortunately, this decreases the value of the public private dialogue. One example is the public health insurance law, a constant hot topic for our industry with only few advances for the better thus far.

When we come back in 2020, what will you have achieved?

I would consider the establishment of a national organization for medicament verification, including choosing the right provider and right financing, an achievement. I consider this an achievement as it would significantly improve the safety for Czech patients. Furthermore, I hope that we successfully change the regulations in a way that medical products are not forced out of the market anymore.

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