Interview: Gintautas Barcys – Director, State Medicines Control Agency (SMCA), Ministry of Health, Lithuania

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Gintautas Barcys, director of the State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania (SMCA), explains the increasingly significant role of the SMCA on a national and European level and highlights some of the most successful initiatives implemented by the institution over recent years.

Can you please introduce the main obligation of the SMCA as well as the evolution of the institution since your appointment as director back in 2008?

The SMCA is the Lithuanian institution in charge of controlling and surveillance pharmaceutical activities in order to ensure that only good quality, safe and effective medicinal products are available to the Lithuanian population.

In terms of evolution, the agency has overall achieved remarkable results, now being able to develop all marketing authorization procedures on time and fully in accordance with the European regulation, which unfortunately was not the case in the past. In this sense, I am proud to confirm that we are also increasing our activities on centralized marketing authorization procedures. Additionally – and this has really defined the evolution of the institution over recent years – the SMCA has strengthened its collaboration with the European Medicines Agency (EMA) and this tight relationship has proved to be very fruitful. We are delighted to see our increasing weight in the European territory and we are looking forward to further increase of our trust within both national

and European institutions.

Expanding on other interesting trends, it is a reality that more and more companies are willing to launch their products to the Baltic region and Lithuania, as the biggest market in the Baltic area, plays a key role on this front. Indeed, eight years ago, the SMCA agreed on a common Baltic procedure with Estonia and Latvia, which has helped to increase the size of the common Baltic market. We have developed similar common package procedures with Poland and, furthermore, we have an agreement with Latvia and Estonia on cooperation in the areas of GMP, GDP, PhV inspections and Laboratory testing. Presently, we are discussing and preparing some new collaboration memorandums with the Dutch and the Italian agencies.

Nevertheless, especially at the beginning, we were facing some challenges to develop some of our activities such as the scarce talent pool. In order to overcome this situation, five years ago we signed a cooperation agreement with the Lithuanian University of Health Sciences, seeking to strengthen the education of the required specialists and clinical pharmacologists. This cooperation has also been really positive and we are already incorporating some young professionals from the University in our institution and in the Ministry of Health of the Republic of Lithuania.

What have been the most recent regulatory changes for medicines approval in the last few years?

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It is a reality that we were facing, and still exists, worrying shortages of some medicines in the market due to parallel exports, amongst other causes. In this sense, we have recently started to implement a monitoring system to track those drugs that are present in Lithuania in order to early indicate and quickly react in front of any possible shortage. The outcomes of this initiative have been really positive and we have substantially reduced permanent medicine shortages.

Nevertheless, such a monitoring program would not be possible without the participation of private stakeholders such as wholesalers and pharmaceutical manufacturers, who submit weekly and monthly reports to us about their stock, the number of packages sold to the pharmacies, among other information. As a consequence, we are now more proactive when facing any shortage, being able to take decisions before the medicine is actually sold out in the market while, at the same time, it has been a great action to fight against counterfeit drugs due to stronger control of the medicines sold at the different sales points in Lithuania.

How easy was it to get the industry on board this medicine monitoring program?

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We certainly needed the collaboration of the private industry – from pharmaceutical manufacturers to wholesalers – to succeed in this initiative. I have to say that it was a challenge at the beginning since companies did not want to share information about their exact number of packages marketed in Lithuania. In fact, by that time, it was quite normal that some hospitals or even directly physicians were calling us because they were lacking of some highly needed drugs in key therapeutic areas like oncology and tuberculosis. Hence, within such challenging frame, we decided to take an action and we organized a meeting with the wholesalers, as well as pharmaceutical manufacturers, to have a direct dialogue about the situation. Satisfactorily, at the end, they understood the importance of giving us the information since it directly impacts the patients.

Considering the vital importance of the SMCA's duty, how are you collaborating with other stakeholders such as government institutions, associations, industry, and patients?

The aforementioned monitoring system is only one example of several industry-government collaborations. In general, we closely discuss with the industry and other stakeholders all the key subjects since they give us really useful feedback about the market as well as our initiatives and, therefore, it helps us to drive our future actions.

In fact, we prepare a feedback questionnaire on yearly basis that we share with the industry and other stakeholders to assess their level of satisfaction with our activities. So far, I am delighted to share that the results from this feedback have been quite positive but we are aware that there are still some rooms for improvement.

What is your assessment of the transparency in the Lithuanian healthcare system?

It is well known that Lithuania was facing some transparency issues in the pharmaceutical industry a few years ago; especially regarding financial help to physicians and other healthcare professionals. Nonetheless, this situation has substantially improved over the course of recent years.

Therefore, we amended our law to force companies to disclose information about programs of market authorizations that are developed with Lithuanian healthcare professionals, which includes financing activities of the scientific international conferences. As a consequence, this law has enhanced the transparency in the Lithuanian pharmaceutical market. I can assure you that we will

continue pursuing transparency and diminishing any risk of corruption in the pharmaceutical industry.

CROs are an important area of investment from pharmaceutical companies in Lithuania and one of the main tasks of the SMCA is the evaluation and monitoring of clinical trials. Having said that, what can be the contribution of the SMCA to continue fostering clinical research investment in Lithuania?

The clinical research arena presents several opportunities, but it is still quite under-developed due to the low collaboration between large hospitals and clinics in the countryside. I believe that we should build up a solid network of clinical trials in Lithuania together with our neighbouring countries in order create a regional clinical development hub in the Baltics resulting in synergies and benefits for all the stakeholders from industry to national governments and patients.

From the SMCA standpoint, we are already fostering such regional cooperation and, indeed, we are currently participating in voluntary procedures at the European level for assessment of applications of clinical trials.

From a mid-term perspective, what is your vision for the pharmaceutical sector in Lithuania and what can the industry expect from SMCA over the next few years?

It is a global fact that the healthcare system is continuously changing but I am delighted to confirm that this dynamism is positively reflected in Lithuania. However, Lithuania still needs to develop Health Technology Assessment (HTA) capabilities in order to ensure that the medicines reimbursed are creating the value expected in terms of patients' life quality and costs of treatment. We started to develop our capabilities in this front in spring of 2017 and we expect to have all the HTA structures needed by 2019.

Expanding on the SMCA's role, we are fully committed to developing HTA to properly evaluate innovative medicines backed up with a proper monitoring system to also follow up on the results after such drug entered to the positive drug list.

It is worth mentioning that one of the major challenges of HTA implementation is the development of the needed digital capabilities. However, I am quite confident about the successful ongoing implementation of this project and the recent implementation of the electronic prescription is a clear example of the advancements in this regard. Additionally, the National Health Insurance Fund (NHIF) in Lithuania is already building a comprehensive as well as transparent database that will not only support HTA's implementations but it will also help all the national health stakeholders to better understand the local health dynamics and needs.

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