Interview: Senda Bahri Hicheri – Director, National Control Laboratory of Tunisia (LNCM)

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06.10.2017

Tags: Tunisia, LNCM, Approvals, Pharma, Market Access

Senda Bahri Hicheri, director of the National Control Laboratory of Tunisia (LNCM), is looking forward to helping Tunisian pharmaceutical players thrive by allowing them to profit from both shorter market access times and an upcoming accreditation for the laboratory. In this interview, she explains the key role the LNCM is playing in the approval of drugs as well as other chemical and personal care products for the Tunisian market. In the near future, she hopes the Laboratory will have the chance to access biotechnologies and biosimilars in-house.

What role does the LNCM play in the Tunisian healthcare system and what are your main responsibilities?

The LNCM is a key structure in the Tunisian healthcare system. It is a public institution, situated under the Ministry of Health's authority. Patients and hospitals depend on the Laboratory's ability to approve the right products in a timely manner. Our role is to evaluate the quality, effectiveness and compliance of medication, other health products and vaccines both before and after their commercialisation. Every single market authorisation the PCT (Central Tunisian Pharmacy) approves is the result of a positive scientific compliance report we issued.

We proceed in cooperation with other public institutions, determining whether drugs and health related products are compliant with the sanitary standards valid in Tunisia. More specifically, we ensure the optimal efficiency of our services at every step of the approval, by collaborating with

the Direction of Pharmacy and Medication (DPM) in charge of delivering market authorisations and consumption authorisations, the PCT and the Hygiene Directorate of Environment and Protection of Environment (DHMPE) in the case of the evaluation of biocides.

Specialised pharmacists and physicians evaluate the file posted by a company intending to bring its products to the market. All aspects of the product are taken into account to determine whether the quality of the product is sufficient and in conformity with our standards. In parallel, our laboratory tests a sample of the product under review. Following both parts of the analysis, the team issues a scientific compliance report they transmit to the DPM so that they may take a decision on the approval of the product.

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As mentioned earlier, the laboratory is involved in pre- and post-marketing controls. Post-marketing quality controls can be required for two reasons. We either control the samples sent to us by the pharmaceutical inspection following their decision to proceed to a randomized quality control. Or we analyse the samples from a medication users and doctors have filed complaints about. Following our test, the product can be removed from the market, or remain there.

What have been your priorities since you were appointed in December 2016?

Following the path carved by my predecessor, I have made it a point to increase our responsiveness. With regards to the industry’s growth, the pharmaceutical industry’s growth and the increasing number of market applications we received, the laboratory was too slow in the production of our analysis. Prior to my arrival, my predecessor had worked with the government for the recruitment of new specialists and in order to determinate where the inefficiencies originated. They had set the goal for the laboratory to shorten the response time on any application so that any application would be approved within one year. These efforts where originating from a public-private dialogue that had started and to this day provides a very positive and encouraging frame for all discussions we have. The delay in market authorisations was one of the main concerns of the private industry, thus, tackling this challenge was primordial on our agenda.

As I was appointed, my team was unsure whether they would meet the target. However, by the end of 2016, one month after I was appointed, we had been able to reduce significantly, by half, the overdue on approval time for medical devices and cosmetic products. Then, our hard work and dedication finally paid off as we reached the target of approving all demands prior to March 2016 by March 2017. This was a true moment of pride and would not have been possible without the team working for the laboratory. Now that we have reached the international standards of 12

months for approval, my objective is to maintain this timeframe over the long term and further reduce it.

Looking forward, I have applied for a laboratory accreditation and OMS pre-qualification of quality standards. The national laboratory for control of medication has already enforced certain quality procedures, but these need to be reinforced and maintained in the long run. The LNCM will gain a significant added value from those accreditations, as they will raise us to the level of international standards.

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Such accreditations could also be beneficial for the Tunisian pharmaceutical trade with foreign countries. Indeed, all exported products manufactured in Tunisia go through the same evaluation processes abroad. An existing market approval from an OMS accredited laboratory could help accelerate the registration procedures abroad. As a matter of fact, many Tunisian pharmaceutical companies already export their products, mainly in French-speaking African countries. They have a great reputation and the laboratory accreditation can only help them improve their performances abroad. Moreover, the OMS itself is pursuing a tactic aiming to see countries like Tunisia follow a flying geese paradigm to see less developed countries on the continent be driven by our advancements. It is a logic we have subscribed to in the past, hosting foreign physicians and pharmacists for educational purposes at the laboratory, and that we are glad to pursue in the future.

The Tunisian government has decided to increase the share of national supply for the Tunisian market from 50 to 80 percent. How will this affect the LNCM?

This is excellent news for the Tunisian pharmaceutical industry provided the laboratory of control can keep up with the increased amount of applications to deal with. The government would be well advised to increase the laboratory’s capabilities accordingly to the national industry’s growth. The expansion of national production could put our responsiveness to applications at risk if nothing is done to increase our capabilities.

Additionally, these last three years have seen demand for medication shift increasingly towards biotechnologies and biosimilars. Tunisian companies are now eyeing opportunities in this field and this should provide the laboratory with an interesting challenge. Seldom, has the laboratory had to deal with biotechnologies in the past. Most of the analysis done in house was generics oriented, the cases which involved biotechnology applications were outsourced to countries with adequate capabilities. If the number of applications in this domain were to increase, the laboratory would

have to develop the matching competences in-house. As a matter of fact, I am currently in the process of deciding which appliances to purchase, and which scientists to hire to face this new trend in Tunisia’s health environment. I expect the laboratory to have one of the first control units for biotechnologies and biosimilars on the African continent, if we take the right steps now.

What assets can the Tunisian healthcare sector base its development around?

Tunisia is a lot more stable than in the past and the government has a clear vision for developing the country. All stakeholders are fully engaged in restarting the economy and can rely on a qualified set of talents to develop within the new segments of the pharmaceutical industry. Furthermore, Tunisia’s historic commitment to the healthcare of its citizens has provided it with a significant advantage in comparison to its African counterparts. The country’s firms should be faster than those of other countries to develop segments such as biotechnologies and biosimilars.

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