Interview: Inès Fradi – General Manager, DPM (Direction de la Pharmacie et du Médicament), Tunisia

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Inès Fradi, general manager of the DPM (Directory of the Pharmacy and Medicine in Tunisia), explains the particularities of the Tunisian healthcare system and the work of the DPM in regulatory affairs as well as its interactions with the other private and public entities. She presents the recent achievements of the DPM in significantly reducing the timeframe for registrations and its ambition to further foster effectiveness and local manufacturing, as well as the arrival of more biosimilar molecules in the country.

The DPM plays a central role in the Tunisian healthcare system. Could you please explain to our international readers the main characteristics of its functioning and the particularities of the Tunisian healthcare system itself?

The DPM, the regulation body for drugs in Tunisia, has made it one of its central focus points to promote transparency. One way for us to guarantee it, is to render most of our activity traceable online. Another particularity of the DPM is that it supervises a very diversified set of activities. We are responsible for the registration of medication as well as for the authorisations for the export and import of drugs, food supplements, cosmetics and medical devices. The latter are submitted to a technical control upon arrival. The DPM also supervises tax clearances of drugs and health related products.

Furthermore, we have a role of overseeing the activities of the pharmaceutical industry and control thereof. Companies of the industry refer to us for any authorisation for major changes and any details regarding their products. The pharmacies also share their sales, transfers and buying activities with us. Moreover, we are very involved in the pharmacovigilance programme. All of these activities are within the state's responsibility and thus in our business range.

Our system is quite particular as well, and very interesting. It has drawn several other African countries to try and replicate it. By the monopole the central pharmacy of Tunisia (PCT) holds on imports and the fact that every drug in the country has to be approved by the DPM, counterfeit drugs are largely avoided. Another particularity of our system is that veterinarian medicines are treated in exactly the same way than human medicines. The controls in place are the same, so it makes sense for us to dispatch the same teams for the control and regulatory affairs of both areas.

The DPM plays a central role in the Tunisian healthcare system, being in charge of the healthcare regulatory affairs. It now faces the challenge to reduce the time for the introduction requests to the market from three years to half the time. How do you tackle this challenge?

There is a very strong will in Tunisia, to develop the pharmaceutical sector in its overall economic weighting and specifically its export capacities, and we have developed a global project to build on our ambitions. Since 2014, we conduct private-public dialogue to identify pending challenges hampering growth and expansion. The time frame is one issue we have been facing, but the price and the stimulation of research and export are equally concerns that have repeatedly been risen.

Once these issues acknowledged, we went on to form public-private think tanks working along different themes and proposing solutions. Within those think tanks we first tried to identify what it was exactly that was holding us back and preventing success and efficacy. In order to do so, we analysed our numbers and for instance saw that one issue was that we were not taking on enough cases and drowning in untreated work. Thus, we raised the pace of treatment of folders just as the pace of submission had raised.

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Our main success points therein were better coordination and the commitment to deadlines. We divided our work load into two piles, one for the folders that had been lying around for long and one for the more recent folders. As of today, I am proud to say that we managed to catch up on our workload and now only work on the more recent submissions that have been on our desk for less than a year. This still leaves room for improvement and we have pledged ourselves to a time frame

of less than a year for any regulatory demand, even if the folder is not complete when it is first submitted.

Have you been able to witness first impacts of these efforts for the pharmaceutical industry and yourselves at the DPM?

Well, of course no one will be able to answer the question of success better than the industry itself. However, I am convinced that first impacts have been felt since everything is developing so quickly here. Since we have been able to speed up the process of registration, the pharmaceutical industry has been considering the launch of new molecules in Tunisia. This is a direct consequence of the improved pace, as the launches have surged as of late and thus the competition has intensified. This increased competition as well as the multiplication of generics bring with them dropping prices and an overall reduced cost for the healthcare system.

The public private dialogues we have been conducting with the industry have been highly beneficial, as they allow us to target our actions to address the problems at hand and react accordingly. The solutions we find are also more concrete, having been elaborated after a discussion where all the concerns have been openly talked about.

When we interviewed Mr. Moez Lidinallah Mokaddem from the PCT, he told us that the next step to address is the creation of one unique central committee deciding upon the drug prices. What is your assessment on the situation?

The process as it is set today is long and involves many actors. The first step to price regulation is the technical committee. Then, if the drug in question is a product of import, the central buying commission is the next player involved. Their responsibility is to decide upon the roll-out of the acquisition, whether it will take the form of a call for tender, if it will only involve the public or also the private sector and so on. And although this commission will follow the price suggestion made by the technical committee most of the time, they have it within their power to revisit it.

The public prices are adapted by the ministry of trade. Hence, locally manufactured products will directly—once they have been approved by the DPM—be submitted to the ministry of trade for their price tag, but only after having received a suggested tag by the technical commission. The last step is the reimbursement. It is treated by the ministry of social affairs, and sometimes, the price can be renegotiated in that instance.

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As Mr. Mokaddem has rightly pointed out, our goal is to create a single commission that will bring together all of the afore mentioned actors. This commission will have the capacity to discuss the price, negotiate it and decide upon the reimbursement. This will also render the system more transparent. Today, an insight into the price of locally manufactured products is possible at the ministry of trade. However, imported products do not systematically offer this possibility.

This is really one of the downsides of the compensation system we have in Tunisia. The sale prices for the drugs to the public are fixed by the ministry of trade and do not fluctuate. Therefore, if the dinar falls or the price of sale to the PCT rises, the margin for the PCT dissolves and worse, can turn into a loss. This difference is shouldered by the PCT, which explains their struggle to be profitable. The system is a good guarantee for the patient as he or she is guaranteed a stable price, but in times of inflation, it is difficult to control.

Tunisia produces 50 percent of the country's consumption in medication locally and aims to increase that share to 80 percent. How do you assess the feasibility of this project?

I believe it to be very feasible, especially thanks to the new technologies we have access to. Of late, we have seen more and more new local manufacturing undertakings coming to Tunisia. I expect this share to grow further and am very optimistic that, step by step, we will reach those 80 percent. However, this goal cannot be reached without a more intense focus on biosimilars and biotechnology products in Tunisia.

At the DPM, we are ready for their regulation! While we had long waiting processes for the approval by a quality commission and then a speciality commission for biosimilars, we have now established a multidisciplinary commission that only deals with the comparability of biosimilars. The experts of tomorrow are being trained today to be able to follow the analysis process for biosimilars, which is very different from that of conventional drugs.

Ms. Fradi, you have been leading the DPM for three years. What main priorities have you been focusing on and what are your upcoming projects?

As mentioned, since 2014, we have been able to significantly shorten the timeframe of our regulatory affairs and dedicated ourselves to ameliorate the transparency of our system. We have further published a very detailed guide on drug registration procedures that is easily understandable and follows the international standards we are committed to.

Our next projects will include the publication of a paper on promotion and medical information. We also wish to further modernise the registration procedures for medicines and drive the participative approach with the private sector and various key stakeholders we have begun to undertake.

Do you have a final message for our readers?

You have to come and invest in Tunisia! The DPM is here to help you with the regulation process, and we have a solid system that is undergoing changes for the better.

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