Interview: Riadh Daghfous â?? General Director, Tunisian National Pharmacovigilance Center (CNPV)

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Riadh Daghfous, managing director of the Tunisian National Pharmacovigilance Center (CNPV), describes the role of the CNPV in side-effect monitoring, pharmacovigilance, and marketing authorizations.

CNPV plays a central role in Tunisiaâ??s health system. Could you explain the CNPVâ??s main operating features, its means and attributions, as well as its interactions with the other bodies of the Tunisian health system?

The National Center for Pharmacovigilance (CNPV) has had the exclusive responsibility for monitoring the adverse effects of drugs in Tunisia since 1984. This responsibility applies during pre-marketing clinical trials, and after a product has been placed on the market. We have established a preventive model through the study of the frequency and severity of the known adverse effects. Ultimately, we are expect to be able to detect the lesser-known and undesirable side effects of drugs. The CNPV is also responsible for monitoring drugs in chronic diseases. The center achieves more than 10,000 dosage controls per year. Finally, the CNPV is preparing one of the few bioequivalence units in the world. It will replace the foreign private companies that are currently carrying them out for Tunisia. The center will be one of few bioequivalence centers, and certainly the most effective in Africa. Before starting, we are looking to obtain its international accreditation.

Currently, Tunisia does not have a drug agency. Therefore, the CNPV is directly affiliated to the Ministry of Health. However, we collaborate with the Pharmacy and Drug Department (DPM) and in some cases with the national drug control laboratory. We also collaborate with other structures such as the basic health care department that manages vaccination programs in Tunisia as part of our role in the surveillance undesirable effects of vaccines.

What were the priorities when you started your term in 2017?

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Strong pharmacovigilance is essential to attracting investments from international laboratories. Therefore, my first priority is to strengthen industrial pharmacovigilance. Some laboratories active in Tunisia do not have pharmacovigilance activities as such. Of course, multinationals are routinely audited and are forced to conduct pharmacovigilance activities, but many local laboratories do not apply pharmacovigilance guidelines. It is essential for us, as an authority, and for the health of Tunisians, that at least one person is in charge of supervising the implementation and enforcement of pharmacovigilance principles within the company.

My second priority is the improvement of our database. The one we are currently using does not allow simple and efficient data crunching. By collaborating with a specialized organization, we should be able to make our system evolve so the information is accessible, applicable, and communicable to the WHO in the most efficient manner.

Thirdly, I would like us to regain the position we had prior to the revolution. We have all the necessary elements to be part of the countries with a solid pharmacovigilance center. Indeed, we have an excellent team that is unrivaled in the world. Most of its members are associate professors in medicine and have worked in university hospitals. Thus, they are absolutely capable of conducting high-level pharmacovigilance.

What have you put into place to achieve your targets?

Tunisiaâ??s data collection of certain adverse effects is unique in the world. More than 3,000 patients are consulted free of charge at the CNPV office in exchange for information on the adverse effects they experience when taking a drug we are looking to monitor. This allows us to communicate the basics of pharmacovigilance serving patients, doctors, and the community.

This initiative only partly resolves the problem. It does not oblige companies to integrate pharmacovigilance to their activities. Therefore, it appears necessary to implement monitoring activities jointly with the pharmaceutical companies. Once enforced, the new Tunisian directives on pharmacovigilance, inspired by the Arab League will harmonize the way laboratories operate, so the market access processes are more efficient and monitoring transparent.

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This directive, adopted by the Arab League in 2014 and adaptable by each country, was implemented in 2015. It will apply to all Arab countries except Morocco and Algeria, whose directives are already close to the ones suggested. Widely inspired by the European guidelines, these directives will enable us to close the gap in the collection of information provided by pharmaceutical companies on their medical products and their undesirable effects. However, the application of these guidelines in Tunisia will depend on the understanding laboratories have of them. Therefore, a training program has been developed to clarify what is expected of laboratories since the application of these measures. The feedback is positive and we intend to reiterate the experience. I hope that this type of industrial pharmacovigilance training will extend to other parts of the world.

Once the laboratories will have started implementing the processes expected from them, our mission will consist of ensuring the long-term enforcement of these processes, especially in the case of local laboratories. This will be beneficial for the patient, the country, and the laboratory itself. Indeed, a mistake in the enforcement of pharmacovigilance processes can wipe out the reputation of a laboratory.

What is the CNPVâ??s role in marketing authorizations?

The CNPV takes part in every commission and has a scrutiny right on marketing authorizations. Our opinion is extremely important in the case of the cancellation of a marketing authorization of a product if we consider it to be dangerous. Adding to this, our expert view allows a reduction in appraisal times of marketing authorizations of products we consider both beneficial to the population and easy to monitor from the point of view of pharmacovigilance. Once a product is placed on the market, we remain in charge of its pharmacovigilance. For this reason, the CNPV supervises the risk management and ensures the monitoring of drugs in compliance with international standards

What partnerships, other than the WHO, can you rely upon to obtain an international accreditation?

We will try to reinforce the collaboration with the European Medical Agency (EMA) as well as with the National Agency for the Safety of Medicines and Health Products (ANSM) in France. Despite the fact we often collaborate with French companies, the CNPV has not yet worked with this agency. Also, we are going to reinforce our collaboration with the African Society for Pharmacovigilance of which I am a founding member.

We widely collaborate with Morocco and used to participate in international reunion but we havenâ??t done so for several of years. I am currently investigating the possibility for us to participate in the reunion with pharmacovigilance directors in Uganda this year.

What are the factors affecting pharmacovigilance?

Worldwide, drug manufacturing has evolved. The chemical productsâ?? segment is slowing down and laboratories are now focusing on the development of biotechnologies. The control of biotechnologies and biosimilars requires more precise pharmacovigilance than for chemical drugs because the effectiveness of a biotechnology depends on the quality of its potency control. Moreover, the control of adverse effects of biotechnologies is more complicated than that of chemical products.

What is the status of biosimilar products in Tunisia?

Since 2008, only a few biosimilars were present on the Tunisian market. Recently, things have started to accelerate. Moreover, this year the DPM organized a special commission on biosimilars chaired by Hachemi Louzir to assess how important they are for Tunisia. Prior to this commission, a biosimilar product registration guide was drafted, which will be reviewed by Tunisian and WHO experts. The CNPV is ready to implement what has been proposed, although some minor changes from the point of view of laboratory control. Moreover, we have already included a chapter on biosimilars in pharmacovigilance training for Tunisian companies.

Where do you see the future of the Tunisian pharmaceutical industry? Towards the export or rather towards the local, that is to say the similar bio?

Nobody knows what the future of medicines will be. Large local producers have heavily invested in chemical products and continue targeting the domestic market because it is still growing. Over half of

the demand is supplied through imports. If the market were to prefer the use of biotechnology drugs and biosimilars to chemicals, I would not be surprised to see that some producers would reorient their investments towards biotechnologies and increase the level of exports of generic products.

It is yet to be determined what the role of Tunisia could be in the production of Biosimilar products if the demand were to change. The design of biosimilar molecules does not require the same technological levels as the distribution of these molecules and this will necessarily have cost implications. These two steps can be considered equally in the definition of local production. In any case, several possibilities exist for Tunisian companies. 50 percent of the local market is yet to be conquered by Tunisian producers and export opportunities exist, mainly in African countries, provided our companies choose the right trading partners.

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