Interview: Mohamed Khalil Tamim – Head of Regulatory Affairs Africa, Alcon Tunisia

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Mohamed Khalil Tamim, Alcon's

head of regulatory affairs Africa manages the regulatory affairs of 47 countries in Alcon's African cluster. He explains the necessity of creating and harmonizing medical device-specific regulatory frameworks in Africa for the benefit of patients, and documents Alcon's strategy to navigate a price-sensitive market despite its high-end product portfolio.

Mr. Tamim, you joined Alcon Tunisia in April 2017. What is Alcon's current status in the country and its possible evolutions?

Alcon Tunisia is a branch office of Alcon Pharmaceutical Ltd. based in Switzerland. The local entity was established in 2007. Prior to 2007, a Tunisian distributor and partner conducted our operations locally. Tunisia is an important market for Alcon, specifically in the North African region. With regards to the evolution of the ophthalmologic medical devices market, it appeared necessary for us to establish a representation office here for promotional activities and relying on local distributor's network supplied by Alcon Pharmaceuticals Ltd from Switzerland.

The early days of the Tunisian branch occurred in the wake of Alcon's transition towards a greater focus on medical devices. Despite the multiple challenges, we managed a smooth transition and established a clear strategy for Alcon's development. Indeed, Alcon reorganized its franchises for the African continent. The African cluster now comprises 47 countries excluding South Africa, which

is managed independently. I hope Alcon Tunisia will become an affiliate of its own.

What is the current state of medical device regulatory frameworks in Africa?

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As head of regulatory affairs Africa, I manage the regulatory affairs activities in every country of the African cluster. Out of the 47 countries under my supervision, 33 have an active medical regulatory framework, and only 13 have a medical device-specific regulatory framework. Unfortunately, Tunisia doesn’t have any medical device regulations and such standards would be beneficial to Tunisian patients, monitoring agencies, and medical device companies if implemented.

Nonetheless, the National Agency for the Environmental and Sanitary Control of Products (ANCSEP) has just started drafting a regulatory framework for medical devices in Tunisia. Their reflection is expected to be effective by 2019. Meanwhile, we’ll be actively attempting to participate to shape this regulatory framework to ensure it promotes both, the interests of the patients and those of medical device companies. I am convinced Alcon’s experience in dealing with regulatory processes around the world can be beneficial for the creation of a medical device legal framework in Tunisia.

ANCSEP’s initiative is extremely important because the requirements for pharmaceutical products differ from those for medical devices. As a result of these regulations or lack of thereof, many medical devices in Tunisia are sold with no means of traceability. Additionally, the border trade resulting from this context poses a sanitary risk for patients. We need to collaborate with the health authorities to provide patients with the highest level of medical safety. As a result of the adoption of the new international standards, illegal border trade would be marginalized and companies with a better understanding of the regulatory framework would bring more innovations to the market, which would in turn benefit the patients.

In many countries, the market access of medical devices is restricted to companies complying with a number of ISO standards such as the ISO 13485. However, these standards have not been harmonized across the continent. Therefore Alcon, and other medical device companies with international operations struggle to apply global processes to their operations in Africa. Moreover, some of our products have different legal statuses depending on the country where they are available. For example, our viscoelastic range is considered a medical device product line in Europe and a drug in Tunisia. More specifically, different legal statuses require us to apply for marketing authorizations under different conditions, which is resource consuming.

Alcon is a global leader in the ophthalmology field, where does the company stand in the Tunisian market?

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Tunisia is the most developed country in the region regarding cataract surgery and Alcon has the largest market share in ophthalmologic surgery equipment. Our products in Tunisia are of two types: installed-base medical equipment and disposable medical devices. Alcon’s branch in Tunisia leads the installed based products with equipment such as Phacoemulsification and retina-specific surgery equipment because healthcare professionals recognize the quality of our equipment and value the traceability of Alcon products.

The most important product lines for us in the ophthalmologic segment are cataract, vitreoretinal disease, and macular degeneration products. We are also looking forward to bringing innovation on the market such as a new generation of equipment allowing surgeons more accuracy and precision.

Alcon strive to be a trusted healthcare partner. Indeed, we are always exploring possibilities to further strengthen our presence in the local market and guarantee Tunisians have access to our high quality and traceable products.

What activities do you engage in to build your brand image?

Following its global policy, either Alcon has a direct presence in a market or has a partnership agreement with a local distributor. In the case of a direct presence the affiliate or branch is in charge of importing the goods, implementing them, and conducting in-store promotion. In the case of a partnership, the distributor receives products from Alcon and is responsible for their implementation in the local market.

Reaching out to healthcare professionals to participate to the upgrade of the scientific community professional practice and education where needed is the most important aspect of our building policy. We strive to make them switch from extra capsular surgical operations to phacoemulsification. In fact, we have offered possibilities of Wet-Lab operations used to provide training to our healthcare professionals. Moreover, Alcon addresses them with a series of roundtables, webinars, and symposiums. We want to share our expertise, so the level of knowledge among eye-care professionals in Tunisia increases. These initiatives are also an opportunity for us to communicate on the quality of Alcon’s products and the safety processes we enforce.

What is the importance of Africa for Alcon, considering that 90% of people with a visual impairment live in developing countries?

Alcon is looking forward to expand its presence on the African continent. So far, the Africa Cluster is managed from offices in Tunisia, Morocco, and Egypt. Morocco plays an important role in the supervision of French-speaking countries on the continent. Egypt is Morocco's counterpart for English-speaking countries in Africa while Tunisia is important because it is the most developed country in Africa in terms of cataract surgery. As a matter of fact, Alcon based on their partnership with imminent Tunisian practitioners in the field of continuing education, will attract healthcare professionals from all around the continent and increase Alcon's influence in the ophthalmologic field in Africa.

Alcon, as a division of Novartis participated to a program called Go Africa. The main goal of this program is to extend patient access to technologies in Africa. Alcon also takes part in many initiatives across the continent including internationally supported humanitarian missions. For example, we contribute to an American-led program in Uganda that provides free surgeries to the population. This initiative is not limited to Uganda, and Alcon provides logistical support for these initiatives in other African countries.

Our presence in Africa appears important for the business despite the multiplicity of challenges we can encounter while conducting operations there. Indeed, tremendous advancements can be made in terms of patient safety in Africa. This prospect combines the incredible opportunity of growing at a double-digit rate with the rewarding sense of contributing to patient safety. Indeed, operating in the African market gives us the opportunity to work with governments on the development of the medical device sector and its regulations.

What are your main objectives for the future?

Our first objective is to bring technology to our patients. We have just received the marketing authorization for a new imaging device that we'll bring to the market very soon. Secondly, we are looking forward to creating a pool of healthcare talents across Africa and we'll conduct a series of Maghreb-wide training webinar programs capitalizing on Morocco's infrastructure for wet labs. Thirdly, we wish to collaborate with authorities for the development and implementation of the new medical device regulation. It will protect the patient and our business by marginalizing illegal border trade and counterfeit product sales. This is a huge responsibility as it affects the safety of patients. Finally, I am looking forward to increase Tunisia's situation in terms of technological access.

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