Interview: Christophe Sauer â?? President, Sephire, Tunisia

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Christophe Sauer, president at Sephire, the association of innovative pharmaceutical companies in Tunisia, talks us through the challenges that innovative MNCs are facing in the country, especially in terms of pricing, but also highlights the important efforts that have been made in public-private dialogues.

Mr. Sauer, could you please introduce Sephire to our international readers and take us back to its beginnings?

Sephire is a union of innovative pharmaceutical companies, so companies who have activity in research and development. It was founded in 2011, the year of the revolution, and the decision was linked to these events. Indeed, during the revolution the general managers of the different innovative pharmaceutical companies were trying to communicate with one another regarding the safety of their employees, because of the situation on the streets of Tunis. We would often be wondering what the other was doing, whether they had stopped working or were starting again, what safety advice they were given or giving. We were sharing all this information, and once these times of insecurity were behind us, we saw the benefit of communicating and decided we should unite and have a common voice. The name Sephire comes from an Arabic word meaning â??ambassadorâ?•. We are the link between the policy makers, the government and the headquarters of our companies.

You represent a series of innovative companies here in Tunisia: Pfizer, Novartis, Sanofi, Roche, Abbott, a long list. What was the rationale for your members to come and open up operations here in Tunisia?

Some of our members have a long-standing presence in Tunisia. The country remains to this date interesting with a sizeable market of almost one billion USD. Compared to the size of the population of 11.5 million inhabitants, this is a good figure. Moreover, Tunisia has an important standing in non-communicable diseases, which are of course an important area for innovative companies such as ours. The will to invest in oncology that has been present since before the revolution is still chief, much more than in other countries in the region.

As a consequence of the so called â??correlation lawâ?• that existed in Tunisia until 2007, a few of our members still have manufacturing activities here. This law stipulated that when a company manufactured a generic product locally, it could ask for â??correlationâ?•, which meant that the originator was banned from the market. The consequence was that you had to produce locally or disappear. Although today, I do not see a real incentive from the government to drive local manufacturing. It would not even have to be a tax relieve, we would be content with better Intellectual Property Regulations (IPR) or more reimbursement on our products.

What differentiates the Tunisian healthcare system in the MENA region, and what are the consequences of this system for the innovative companies you represent?

The most important specificity of the Tunisian system is the PCT (Central Pharmacy of Tunisia), which gives Tunisia a central body that has the monopoly on any medicine that is being imported. This is very different from any system in the region.

The PCT is buying in hard currency and selling in dinars to the patient. Therefore, the patients are protected from fluctuations in exchange rates, but the PCT has to pay for the resulting difference. It has been facing some issues of late.

Because the situation is so stressful for the PCT, they asked the originators to lower their prices. However, we already gave Tunisia a really good price to begin with, and even for the local manufacturers it would have negative consequences as they would have to lower their price compared to ours. We would be in favour of letting the prices fluctuate according to the currency. Not only would this be much better for the PCT, the patient could freely choose between the generic and the brand.

When we met Ms. Fradi of the DPM (Tunisian medicine control agency), she told us of the efforts they have been made to reduce the time to market. Has this trend been noticed by the industry?

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In 2014, under the umbrella of the World Bank, public private dialogues were introduced. They touched upon different tropics amongst which the most important were pricing and time to market. In terms of time to market, the efforts made were important and it has improved a lot, something we are noticing as well. I am confident that by the end of the year, we will get responses in less than a year, probably in about nine months, which is a considerable improvement if you consider that one year ago it took about three to four years for one product to go through the whole process of approval.

In general I have to underline how beneficial those public private dialogues have been; they helped build trust and understanding between Sephire, the government and the CNIP (association of local manufacturers).

What other challenges do you still consider need to be tackled in the Tunisian system in order to improve the situation?

The next issue we need to tackle is that of pricing and reimbursement, both linked for us innovators. At the moment, the rules are not transparent if at all present. The system provides a marketing authorisation at the same time than the pricing. Only after can you send a request for reimbursement to the CNAM, and there is no room for negotiation in doing so. Also, the rationale behind why a product is accepted for reimbursement and another is not, is not communicated to the companies.

When we bring a new product to the market it will most likely be a biological product, and, unless it is being reimbursed, it will not reach the patients. Likewise, we cannot begin by giving a good price to the PCT if we do not know beforehand whether the product will be reimbursed or not and hence do not know about the volume we will be able to sell. If the reimbursement decision were to be taken at the same time than the pricing, we would be able to have a better estimate on the quantity we will be selling and it would be easier to agree on a price.

Since the public-private dialogues have started, we have heard tell of a unique pricing committee. This is still a work in progress however, and involves not only the ministry of health, but that of social affairs, finance, trade and industry.

Another point is that the pharmaceutical market has been flat for the last five years. If we want to achieve growth we have to have products in our portfolio that are being reimbursed by the state.

Regarding Tunisiaâ??s advancement in biosimilars, what is your assessment on the situation in Tunisia?

Some biosimilars have already been submitted, and are currently being assessed at the LNCM (National Laboratory of Medicine Control). Thus, biosimilars are already on their way and there is a plan to implant a technopole in Sidi Thabet. Tunisia had to catch up some of its delay in the registration process which made originators come late and generics even later. The improvement on the time to market joint to a potential law encouraging biosimilars will allow the country to develop its own biosimilars, it is a possibility.

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Mr. Jeribi, your predecessor, was also pushing for Tunisia to become an excellency centre for clinical trials. How do you view Tunisiaâ??s potential in that regard?

This is indeed a very important project for Tunisia, and the country has the potential to become such a centre of excellence for clinical trials, as it already has the required legal framework. Last year there was a change in the regulation of the Institutional Review Boards in Tunisia. There are now three of them, and not one for every single hospital. This makes the applications much easier and time worthy.

Furthermore, Tunisia already has a good CRO presence as it has been a testing ground for clinical trials before, being the third country in Africa behind South Africa and Egypt in terms of number of trials realised. In addition to that, it has the required workforce and presents good options for an exit plan which is in turn linked to the time to market. So, by improving the time to market, the DPM has improved Tunisiaâ??s potential in clinical trials. I personally am a big advocate of clinical trials, as they help to improve the quality of medicine.

What are the key priorities for the next years at Sephire?

In 2011 our priorities were the pricing, the time to market and more efforts on ethics and the encouragement of clinical trials. Today, I can say that the time to market has been improved significantly. Our new areas of focus are pricing, biosimilars, better IPR and ethic. It is very important

for a country to invest in biosimilars and most new products reaching the market today are biologics. As with generics a few years ago, the challenge is to not only bring the product to the market, but to ensure that those products are of good quality.

Tunisia has been and is still an innovator friendly country, but the budget issues the PCT and CNAM are facing are too much to handle and need to be adjusted urgently. The situation is unbearable for the PCT, CNAM, for Sephireâ??s members and for the local manufacturers as well.

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