Interview: Jade Salhab Senior – Private Sector Development Specialist, World Bank Tunisia

"If Tunisia wants to be a leading country in terms of exports in the pharmaceutical sector it needs to continue along the lines of what is currently being done in the PPD."

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Jade Salhab, senior private sector development specialist at World Bank Tunisia, discusses the impact of the public-private dialogues initiated by his organization in Tunisia, and the additional measures needed to improve healthcare outcomes in Tunisia

The World Bank, in response to a request from the government of Tunisia, facilitated a series of public-private dialogues (PPD) in the country starting 2013, Why was such an initiative necessary, specifically in relation to the Tunisian pharmaceutical sector?

The post-2011 political atmosphere allows for dialogues in which people can express themselves freely without any constraints or restrictions. This kind of initiative is essential for policy makers to understand the specific challenges faced by firms, and facilitates the implementation of policies that support a competitive and resilient private sector. In this case the Competitive Industries and Innovation Program (CIIP) funded this pilot initiative, which was meant to explore this new approach, and hopefully spread it to other sectors across the economy.

The PPDs engaged government authorities, local companies, as well as multinationals. Four pilot sectors were covered, including pharmaceuticals (human medicine, to be more specific). The government had a particular interest in developing high value added activities, providing the basis for an alternative economy; one built on innovation and high levels of knowledge.

The idea of the project was to pioneer a bottom-up, analytically-underpinned, participatory reform process. In other words, the project aimed at implementing a participatory-led set of reforms in Tunisia to increase exports and competitiveness, but it also aimed at informing that process with rigorous analytics, so that identified reforms are genuinely beneficial to pro-growth firms, and their effects are sustainable on the sector and the economy at large.

The elements necessary to develop a strong Tunisian pharmaceutical sector were already existent. In fact, when the PDD begun, 50 percent of the domestic market's needs were already covered by local production, and talent was readily available. The sector offered promising perspectives for engaging in higher added-value activities.

Leveraging the Bank's convening power and credibility among actors in both the public and private sectors, our role primarily consisted of facilitating dialogue between parties whose interests sometimes differ. It is of utmost importance that we preserve our neutral position so that information can be exchanged freely and interventions are trusted by all as impartial.

The participants have championed the project and, at the end of the day, the innovators and entrepreneurial people, both public and private, are the ones that came up with the ideas to reform the system.

How will the project help unleash private sector growth, what discussions have you had so far, and what have been their outcomes?

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We organized the process in three phases: first, the identification of constraints to exports and competitiveness; second, the development of an action plan to address these constraints; and third, the implementation of some of these actions when this was possible within the time and resource limitations.

We started with an independent analysis followed by a three-day intensive workshop between most of the actors in the sector. Seven binding constraints on exports and competitiveness of the pharmaceutical industry in Tunisia were identified. Among these were delays in marketing authorization and medical appraisal, distortions resulting from the current pricing system, underdeveloped clinical trial regulations, and the inefficiencies resulting from the multiplicity of medicine-related regulatory bodies.

After the first phase of identification, we moved into the second and third phases. Actors were organized in different working groups composed of governing authorities, public representatives,

private multinationals, and local companies. Their exchanges where informed by analytical outputs produced by specialized consultants. Their objective was to uncover solutions and reforms necessary to overcome the identified binding constraints.

Let me give a short description of the works in each group.

Getting marketing authorization used to take up to two and a half years. This meant that a company would lose time before products could be launched in international markets. By temporarily reinforcing the resources of the National Laboratory for Control of Medication (LNCM), and streamlining some of the processes, the PPD helped reduce the appraisal time to less than a year. This progress is about to be consolidated through new regulatory texts.

Secondly, the pricing process was fragmented, resulting in a perception of opacity and lack of coordination by many private sector firms. The process often stifled the capacity of local firms to export, as a result of unfair pricing (especially pricing revisions in the context of the devaluation of the Dinar): indeed, the price of products in exported markets is often weighed against the price of medication in its domestic market. The system also prevented a comprehensive approach to pricing, limiting the ability of the government to adequately incorporate in the price fixing process the perspectives of the national health insurance system, or its own public health priorities. The efforts of the PPD aimed at aligning all involved actors behind the creation of a single pricing commission, offering a more comprehensively substantiated, transparent, and efficient pricing process, in alignment with international best practices. This reform is on the cusp of being achieved.

Thirdly, devaluation often distorted competition in favor of imported finished products. Tunisian local production costs rose as the dinar depreciated. On the other hand, the Pharmacie Centrale de Tunisie (PCT) absorbed the difference between the price of imported finished products when they were bought, and the price they are sold at in dinars when redistributed. This, de facto, creates more favorable terms for imported finished goods that have a local generic alternative, while also creating a significant stress on the PCT’s balance sheets. A government decision has already been taken – but not yet implemented – to eliminate this distortion for all products that have local generic alternatives, while the new single pricing committee will help remedy the problem for the remaining drugs.

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Fourthly, one working-group focused on clinical trial activities. If Tunisia wants to become a major exporter in the future, it had to improve the regulatory context for clinical research. The clinical

trial working group facilitated reforms that brought the Tunisian regulatory framework for clinical research to meet European standards. They are now trying to develop the same for clinical research on medical devices.

The last working group focused on identifying segments in the pharmaceutical market that stand to be most promising for Tunisia, and a study on future scenarios of growth have been made and distributed to participants.

And finally, the PPD identified the need for a single drug agency to replace the seven regulatory bodies now involved in the pharmaceutical sector. This reorganization will increase the efficiency of the entire regulatory system, which in turn will benefit companies operating in Tunisia and abroad as well as enable the Tunisian population to access medication more quickly.

One of the main challenges in the case of PPD outcomes is their long-term application and effect. What has already and should be put into place to ensure the outcomes of the PPD are maintained in the long-term?

Long-term enforcement is not a PPD-specific problem, the sustainability of actions being a valid question for any reform. That said, I agree, tracking the long-term enforcement of reforms is a condition for success anywhere reforms are implemented.

For example, the Ministry of Health was considering a decree that would commit regulatory authorities to the reasonable marketing authorization and medical appraisal times achieved, namely a one-year timeline. In doing so, one ensures that authorities will put everything in place to achieve rapid market authorization responsiveness. This would be a bold decision, and it is being considered with due care and consultation.

Another example, in terms of price sustainability, is the merging of the four involved agencies in setting the price of medication into one single pricing committee. This would be a major and durable reform. It would certainly help Tunisia recover a leading rank in terms of the regulatory environment for the pharmaceutical industry in Africa.

Looking into the future, which additional reforms have to be implemented to increase Tunisia’s competitiveness in the sector?

If Tunisia wants to be a leading country in terms of exports in the pharmaceutical sector it needs to continue along the lines of what is currently being done in the PPD. The creation of a highly efficient drug agency, would help the Tunisian export segment remain ahead of the curve.

Additionally, the Tunisian pharmaceutical sector remains somewhat scattered. Tunisian firms are still conservative in terms of acquisitions. I believe greater consolidation could be beneficial for Tunisian export levels. Indeed, larger companies could have greater ability to penetrate new markets.

Lastly, Tunisia should be pursuing a more aggressive investment strategy to enter higher added-value export segments. Indeed, Tunisia has huge potential but is only using it to export limited added-value products. Instead, capitalizing on the highly-qualified talent pool in the country and pursuing the right investments could help the economy transition towards higher added-value activities.

In 2015, Tunisia's pharmaceutical sector stood at TDN 1.8 billion (USD 737 million) and had been growing at an average annual rate of 15% since 2005. What is the current situation of the pharmaceutical sector in Tunisia?

I am confident the sector will continue growing this way, but it must not become complacent. Some low-hanging fruits will allow the pharmaceutical sector to grow at least ten percent annually for the next five years. For example, Tunisia only exports around six to ten percent of its national production. This rate could easily be increased to 20 percent considering the bordering markets such as Algeria, Libya and Sub-Saharan Africa. I believe that these markets will help the Tunisian sector maintain a relatively high growth speed, but the sector's growth in ten years is directly related to Tunisia's investment levels today.

That said, a structural transformation might be necessary if Tunisia is to follow the rapidly evolving industry. I am particularly thinking of biotechnology. More exposure to international competition is a good way to stimulate positive disruptions and catalyze investments within the country, accelerating the race towards innovation and competitiveness at regional level.

Which segments will be driving development in the next five years?

I would say that biosimilar products and medical devices are key. Some investments have been made in the case of biosimilars, with some firms already penetrating this segment. For example, the Sidi Thabet BioTechpole aims to provide adequate resources for companies to develop biosimilars in Tunisia. However, it remains a piece of real estate and further investments should be, and are being, pursued for the BioTechpole to realize its objective.

Similarly, the medical device sector in Tunisia is promising, considering the strength of the Tunisian health sector, its plastics and electronics industry, and the well-trained labor pool. This is a large and fast growing market in Europe, so Tunisia stands to win from targeting it more proactively.

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