Merck – Karim Bendhaou, President for North & West Africa



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*The Managing Director for North West Africa outlines his philosophy of technology transfer and the importance of involving local content in 'fill-and-finish' manufacturing so that the host country is empowered to scale the value chain.*

Can you please start by introducing Merck in North Africa and in particular Algeria?

Merck is a leading company for innovative and top-quality high-tech products in the pharmaceutical and chemical sectors. Around 39,000 employees work in 66 countries to improve the quality of life for patients, to further the success of our customers and to help meet global challenges. It is the world's oldest pharmaceutical and chemical company. Since 1668 our name has stood for innovation, business success and responsible entrepreneurship. The founding family remains the majority owner of the company to this day.

Our biopharmaceutical division, Merck Serono, focuses on specialist indications where there are high unmet medical needs. We also have a special expertise in combining drugs and devices to create intelligent solutions. In Algeria, we have a long-established record having been present with these prescription drugs as far back as the early 1960s through a French affiliate called Laboratory

Lipha.

Algeria is part of the company’s North & West Africa region which groups together some 40 countries. While we have seen some large-scale champions emerge in recent years such as Nigeria, I can confidently say that Algeria remains a key country for us.

In addition to our regional headquarters based in Tunis, we have an office in Casablanca and are present in the Libyan market. Furthermore, we’ve expanded our presence to Nigeria, Ghana and Ethiopia. Our office in Algiers is the largest for Merck in North & West Africa and it is where our quality assurance capability for the region is based. Soon, we will have several products that will be produced locally in Algeria.

How then would you describe Merck’s approach for North African markets?

All over the world, we are actively working to address global health needs through our four areas of medical innovation. Firstly, through the innovation of novel medicines for diseases with high unmet need. Secondly, we are managing the life cycle of our CMC portfolio to address many of the world’s emerging non-communicable epidemics such as heart disease and diabetes. Thirdly, we are developing biosimilars that offer new approaches to access for sophisticated biologics. And lastly, the Praziquantel Donation Program throughout Africa that is addressing schistosomiasis, a neglected disease afflicting populations in emerging health care systems.

With regards to Africa, Merck has its own philosophy on how to do business on this continent which stems from the idea of always working alongside local partners and hiring local people. Many African countries, Algeria included, are very eager to transition from importation to local production, but this is not something that can just be parachuted in from afar. Building your own industrial base is actually part of a gradual process that involves a shift in mentality. There is a certain sequence that has to occur, which takes time and persistence.

Firstly, there has to be the genuine desire from within for the country to assume ownership of the supply side of the pharmaceutical value chain. Secondly, there has to be a transformation of mindset into thinking like a producer. Thirdly, there has to be a level of development in terms of human capital to bring that initial desire to fruition. For these reasons, Merck’s preferred approach in Africa has been to refuse the implementation of a production facility where the company is the sole proprietor.

We are also realistic as to what can be achieved within certain timeframes and of the parameters that we are dealing with. Any company doing its due diligence would quickly identify the

differences between the sort of manufacturing that is expected of a large multinational company with significant turnover, and the level of production that the existing Algerian market is currently geared up to support.

Last year you signed a production agreement with the Algerian laboratory, Novapharm, for the manufacture of medicines for diabetes and hypertension. This project aims to produce 300 million tablets per year at Novapharm's Bou Ismail facility and is estimated to create 150 new jobs. What is the status of this project today?

We believe that partnering with local entities is an essential step in conducting a successful business in Algeria. Our joint venture with Novapharm is perfectly in alignment with the broader strategy for North Africa. Instead of trying to "go in alone" we identified the best local partner in the segment that we wanted to enter. Novapharm was the obvious choice because they had an impressive track record over a number of years of marketing and selling products for the treatment of diabetes and hypertension which are the therapeutic areas where we feel we have the most to contribute.

We perform regular in-depth audits at the new facility and have been demanding very high standards with zero flexibility on any issue related to quality. I am confident that when we commence production within a few weeks, there will be no difference between the German and the Algerian manufactured products. Our local partner has been highly committed to reach this level of quality and to implement international standards for manufacturing.

Can you please tell us a little about the production process that Novapharm employs when manufacturing Merck's products?

Our primary product is an oral anti-diabetes medication. Presently the local workforce is well versed in Merck's standard operating procedures and a real manufacturing mindset has been developed. In addition, the Bou Ismail facility undertakes virtually the entire process right up to packaging. Aside from the active principle ingredient (API) which is imported directly from Europe, from either one of our facilities in Germany, Switzerland or France, everything else is completed here on-site in Algeria.

The Bou Ismail facility has also been supported in its efforts by the National Laboratory for the Control of Pharmaceutical Products (LNCPP), through the early establishment of certification which has been greatly beneficial to facilitate the work and make headway.

The joint venture between Merck and Novapharm was drawn in accordance with the "51/49 percent" ownership regulation which requires foreign investors in Algeria to join forces with a local majority partner. To what extent does this specific ruling represent a barrier to multinationals entering the market?

The 51/49 percent ownership requirement could be a matter of concern for a foreign investor out of fear of losing control over business. Nevertheless, contracts still permit to influence the structuring of the factories and the fabrication units, so in this regard Algerian law does allow for a certain degree of flexibility and permissiveness between pact partners.

The joint venture that Merck has set up very much answers the authorities' call for more local manufacturing. Despite the government's target of 70 percent local production by 2016, domestic manufacturing remains somewhere at the 35 percent mark. What is holding up progress on this front?

The ratio of local production may seem not to be increasing as fast as expected, however the trajectory is a good one and it is positive that the local industry is putting down its roots. There has also been tangible progress made in the areas of healthcare and life sciences. Essentially, Algeria has made an extraordinary choice in mandating that healthcare should be free-at-the-point-of-delivery for virtually the entire population. This is a remarkable scenario for an African country and one that Algeria should be rightly proud of. That is real progress in enhancing access to medicine. Also it would be misguided to see the increase in the national pharmaceuticals bill as a wholly negative phenomenon. This is really a reflection of the fact that more and more citizens are gaining access to expensive but effective therapies that were previously out of reach.

What then do you see as the optimum roles for the government and private enterprise in promoting the growth of the local pharmaceuticals industry?

Private enterprise has the potential to play a very active role in the development of Algeria's pharmaceutical industry in terms of training, technology and know-how transfer, such as good manufacturing practices, quality assurance and pharmacovigilance.

These days, half of the 100 leading products on the market derive from biotechnology. While biotech capabilities grow exponentially worldwide, accessibility in Africa remains very limited. What is it realistic for Algeria to achieve in the biotech domain?

It has to be said that production according to biotechnology processes is formidably complex. The path to success in biotechnology is strewn with pitfalls. Many European and North American firms

have attempted to produce biotech products and have failed, because, at the slightest variation in temperature and blending, you can render the product inactive or, even worse, toxic. Algeria should go slow and first start with “fill-and-finish” manufacturing before setting up a biotech industry. That way the local industry can gain experience by learning how to handle live products where the dosage and temperature require a high level of control and where high attentiveness to avoiding contamination is imperative. It would also enable the local market to gain the requisite knowledge and skills in analysis and verification which is an essential part of the biotech process.

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