Salim El Guermai – CEO & Head Pharmacist, Galenica, Morocco



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Salim El Guermai, CEO & head pharmacist of Galenica, a leading generics company in Morocco, presents the original mission of the company to provide high-quality affordable medicines to Moroccan patients by developing and manufacturing its own portfolio as an alternative to expensive imported drugs. El Guermai also shares his ambitions to develop internationally in Africa, the Middle East and now Russia after receiving GMP certification from Russian authorities and voices his expectations towards authorities to help the local pharmaceutical industry develop both locally and internationally.

Could you start by introducing the activities of Galenica?

Galenica was founded more than 40 years ago by my father Abdelghani El Guermai in order to provide life-saving medicines to Moroccan patients which were unavailable on the market. Building on the first successes and the recognized quality of our locally produced drugs, it quickly became clear to us that it was more than necessary to make essential medicines more affordable by providing an alternative to expensive drugs imported by international companies.

Since then we have developed a wide range of about 280 generic prescription drugs as well as OTC products which we produce at our manufacturing facility in compliance with the latest standards and regulatory requirements. The entire drug formulation and process development is performed

in-house, and 99 percent of our turnover is generated through our own products, ensuring our independence.

Every day, 100,000 patients use our medicines. Our products are present in pharmacies as well as the public market through the tenders of the Ministry of Health. After focusing for a long time on acute illnesses, we are now much more engaged in the treatment of chronic conditions such as cardiovascular diseases, diabetes, and CNS disorders. We have recently introduced generic versions of the newest treatments against hepatitis C which were extremely expensive but badly needed in Morocco as there is a high incidence of the disease.

Beyond Morocco, we have internationalized our operations and are now present in 22 countries through sales and marketing agencies, most of them in Sub-Saharan Africa, but also in Iraq, Libya, and Djibouti. Most recently, we became the first and only African company to be certified by Russian authorities.

When we met with Layla Sentissi, Executive Director of the Moroccan Association of the Pharmaceutical Industry (AMIP), she explained how locally produced generics have developed despite the absence of legislation encouraging prescription and substitution. A new IQVIA study puts generic penetration at 40 percent by volume in the private market in 2018. Do you think it is enough, and what do you expect in terms of policies to encourage the use of generics?

I think the priority should be to strengthen trust in locally produced drugs in general. While most doctors think that originator products are imported, the truth is that most are produced locally by companies that also manufacture generics. Whether they produce originators or generics, every Moroccan pharma company must comply with international quality standards as they are inspected by the National Laboratory of Drug Control which is prequalified by the World Health Organization (WHO) and accredited by the European Directorate for the Quality of Medicines & Healthcare (EDQM). We need to make sure doctors and pharmacists understand that they trust the quality of Moroccan drugs, and in particular Moroccan generics. Multinational companies are partly to blame as they have taken the habit of sowing doubt about the quality of Moroccan generics to promote their products.

More generally, access to medicines is limited by the absence of universal health insurance coverage. As a matter of comparison, the consumption of medicines is much higher in Algeria and Tunisia than in Morocco, at least double per inhabitant, thanks to high public health insurance

coverage. While authorities claim that about 60 percent of the population is covered by some form of public health insurance, I question the accuracy of this statement.

One of the challenges in Morocco is how to cover unreported workers in the black market. As these people do not have health insurance and cannot afford treatment, they wait until their condition worsens to see a doctor. Moreover, due to the lack of access to healthcare services and deep-rooted cultural beliefs, many people prefer to use traditional home remedies instead of pharmaceutical drugs.

The country also needs to invest in its public hospital infrastructure, equipment and human resources, which are not up to international standards. By expanding health coverage and improving the quality of its hospitals, people will have better access to health services and medicines.

Another crucial point which needs to be addressed is the unethical and unlawful promotional practices of some actors which create an unfair competitive environment and lead to public mistrust in the pharmaceutical industry. There needs to be a thorough cleansing of the industry in that respect.

Last year, new legislation made bioequivalence (BE) studies mandatory for generics to receive marketing authorization, which is standard in developed countries. What is the impact of this law on the generics industry?

As we carry more than 200 products in our portfolio, we are not able to afford BE studies for all of them in such a short time. In my opinion, if authorities want the pharmaceutical sector to develop internationally, they should support us in financing these studies which can cost between $20,000 up to $100,000 depending on the centre.

Moreover, the first centre for BE studies at the Cheikh Zaid University Hospital, which opened its doors in 2015, is not yet certified by international regulatory bodies and, as a result, we cannot submit dossiers abroad. Also, there is no official list of BE study centres which are certified by Moroccan authorities.

After a period of high growth following the introduction of AMO, the Moroccan pharmaceutical market has been stagnating after two rounds of price cuts in 2012 and

2014. How have you adapted to continue growing?

Market growth is indeed very low at about two percent, while more actors have entered the market, increasing competition in an already tight environment. In order to continue growing, we have followed a two-pronged strategy. First, we are focusing on bringing niche drugs where competition is less fierce. Second, we are growing our international presence by developing exports and entering new markets.

A few years ago, Galenica introduced generic versions of Gilead's Hepatitis C treatment Sovaldi and BMS' Daklinza at a price 60 times lower than the originals, and the treatment was added to reimbursement lists. How has this improved access to treatment and health outcomes for patients suffering from this viral disease?

Unfortunately, the lack of screening remains a hurdle to improve access to treatment. The government introduced a national plan to eradicate the hepatitis C virus (HCV), but did not follow through with active screening measures. While the Ministry of Health announced that there are about 600,000 Moroccans infected with HCV, we are still looking for them.

Galenica has developed its activities beyond Moroccan borders and is now present in more than 15 countries in Africa and the Middle East. What are the main challenges to expanding in Africa, and what has been the key to your success in the region?

The key to being successful is to deliver quality medicines at an affordable price in a timely manner and the required quantity. We are facing tough competition, especially from Indian and Chinese companies which can easily supply the needs of small Sub Saharan markets. However, we differentiate ourselves with the reliable quality of drugs which complies with European standards, while many Indian and Chinese companies are facing quality issues.

In general, made in Morocco drugs are trusted by African countries, and considered as good as European drugs. Moreover, African countries are more open to collaboration with Moroccan companies as we share a common history and cultural ties.

In 2018, you became the first and only African pharma company to receive GMP certification from Russian authorities to be able to export to Russia and other countries

in the Eurasian Economic Union. What made you decide to embark on this project?

The opportunity presented itself and we seized it. Russian authorities have high standards and are very meticulous and knowledgeable. A team of four inspectors conducted a thorough week-long audit. Receiving GMP certification was a challenge and we are very proud of what we have achieved. The next step is to register our products, and we hope to receive a first marketing authorization within the first semester of 2020. We are currently under discussion with local companies for marketing and distribution.

As a whole, the Moroccan pharmaceutical industry only exports 10 percent of its production even though manufacturers have spare capacity. What do you see as the main hurdles to exports and what should be done to position Morocco as a pharmaceutical export hub?

First, as previously mentioned, authorities should support us in conducting BE studies which require substantial investments in time and money. On the diplomatic side, the government could do more to strengthen relations between local and foreign regulatory authorities and facilitate regulatory affairs procedures for Moroccan companies in foreign countries, for instance through mutual recognition agreements.

What are your priorities to continue developing the family business during this decade?

We will continue to fulfil our social mission to address the therapeutic needs of Moroccan patients by delivering affordable medicines and never compromising on quality. Our ambition is to upgrade our capabilities to be able to develop and produce the latest biological therapies.

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