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Layla Sentissi, executive director of AMIP, Morocco's oldest pharma association,

explains the structure of the country's pharmaceutical industry and its key developments, lays down her ambition to create a National Pact for Medicines, discusses the key challenges for the local industry, and invites global decision-makers of to the Africa Health Business Symposium in Casablanca.

Could you start by introducing the role of AMIP and its members?

In Morocco, according to Law 17-04, Article 74, in order to apply and receive marketing authorization, companies must hold the status of Industrial Pharmaceutical Establishment (Etablissement Pharmaceutique Industriel, EPI) with their own production, control and storage site. All our members have this status.

Companies without their own manufacturing operations in Morocco must thus partner with local firms in order to market their products. Out of 280 foreign companies with products on the Moroccan market, 260 market their products in partnership with AMIP members. In addition, many of our members also market their own products. As a result, our members generate about 75 percent of total pharmaceutical sales.

This model has enabled the development of a strong local pharmaceutical industry which is able to produce the majority of medicines needed by patients. The percentage of drug needs catered to by local production is one of the highest in Africa. In addition to improving security in terms of supply of medicines, the system also brings security in terms of quality because it is much easier to hold local producers accountable compared to representative offices. The National Laboratory for Drug Control (Laboratoire National du Contrôle des Médicaments, LNCM), which is prequalified by the World Health Organization (WHO) and accredited by the European Directorate for the Quality of Medicines & Healthcare (EDQM), evaluates technical dossiers for marketing authorizations, conducts regular inspections to ensure the quality of APIs and finished products, and investigates potential quality issues.

What have been the key developments of the Moroccan pharmaceutical industry?

The implementation of the Mandatory Health Insurance (Assurance Maladie Obligatoire, AMO) in 2006 boosted the pharmaceutical market with around 9 percent annual growth between 2006 and 2012. In 2012 and 2014, price cuts were introduced which resulted in the stagnation of the market. Volumes did not compensate for lower prices.

The Minister of Health in office at the time had promised compensatory measures and higher volumes which would result in better access to medicines. However, volumes did not compensate for lower prices, demonstrating that price reductions are not necessarily the best tool to improve access.

As a result of the narrow local market, companies have turned increasingly outwards. Since 2010, exports have been steadily increasingly as companies enter new markets. However, this increase is not enough to make up for the stagnating local market. One major hurdle is that the narrow and fragmented local market does not enable economies of scale in order to improve competitiveness on international markets. This being said, local manufacturers are putting a lot of effort in conquering foreign markets where Moroccan medicines are perceived as high quality.

What are the main projects you are working on?

We are working on several projects in collaboration with the government to foster the development of the industry. Besides AMIP, there are two other industry associations defending the interests of their members, LEMM for multinational companies, and AMMG representing local generics

companies. We wish to give birth to a National Pact for Medicines federating the different stakeholders around common goals in order to bring real added value to citizens while enabling the development of a sustainable and successful local industry. At AMIP, we consider that local production is the foundation of our industry, and we expect our government to implement tangible initiatives in favour of local manufacturing. Politicians often declare that they are encouraging local production, but the reality is different. For instance, there is no preference for locally manufactured drugs in public tenders, which is the case in Egypt, Tunisia, Algeria, Lebanon, Jordan and Turkey. The importer of the original drug, which costs several times more than the locally produced generic, can lower its price to win the tender. In fact, there were some cases of dumping which were brought to the Competition Authority (Conseil de la Concurrence).

Another important project is the development of clinical studies in Morocco, both for generics and innovative drugs. Last year, a decree on bioequivalence was introduced which makes it mandatory for generics to prove bioequivalence to the original product before being granted marketing authorization, which will encourage more bioequivalence studies to be performed here. The centre for bioequivalence studies at the Cheikh Zaid university hospital is at the cutting edge in this field. Moreover, clinical studies for innovative treatments would bring a lot of added value and savings to the Moroccan health system. We have an interesting patient pool with an epidemiological profile similar to developed countries. However, legislation on biomedical research is still lacking and we are pushing for it. Nevertheless, Morocco possesses the necessary infrastructure and competencies with university hospitals, private clinics, and CROs, to welcome clinical studies. Moreover, the National Center for Personal Data Protection has made health data its priority for 2020.

Finally, we are working with the WHO on prequalification of some medicines in Morocco. We will organize a symposium in April on this subject. The company Maphar has received WHO prequalification for an antimalarial drug. We would like to see more examples like it.

Continuing on the topic of local production, some foreign companies circumvent Law 17-04, Article 74 by creating small production sites in order to receive the EPI status and apply for marketing authorization, but then import drugs. How are you defending the interests of your members against this practice?

First and foremost, we welcome foreign investments in local production in Morocco as they can only benefit the competitiveness and quality of Moroccan drugs. However, we deplore cases where companies establish themselves in order to import most of the drugs they sell.

We want foreign companies to produce locally as the environment is attractive. We have a skilled workforce and managers, and the government has implemented ecosystems to incentivize local production.

What we would like is for marketing authorizations not to be granted for drugs that are produced or producible in Morocco, as is the case in Algeria. In fact, the Algerian model was originally inspired by Morocco, but we are going backwards against the logic of industrialization and economic development.

Regarding generics, how does the government encourage their consumption?

While there are talks of a promotion plan of generic drugs, clear policies towards doctors and pharmacists to encourage the prescription and sale of generics are still lacking, and generic drugs have developed despite the absence of these policies.

The government has the ambition to extend medical coverage to most Moroccans. What progress has been made towards this goal since the introduction of the Mandatory Health Insurance (AMO) in 2006?

According a recent strategy presentation from the National Agency of Medical Insurance (Agence National de l'Assurance Maladie – ANAM), the objective to cover 90 percent of the population should be reached by 2025 if all goes well.

Obviously, the industry as a whole is favourable towards this strategy, and we await with impatience the implementation of a universal health coverage. Unfortunately, there have been delays in the introduction of implementation decrees. Today, AMO covers public and private sector employees who represent a third of the population. The Medical Assistance System (Régime d'Assistance Médicale -RAMED) covers very low-income people who represent another third. However, independents, who represent the last third, or about 11 million people, are not covered by public insurance yet. Moreover, less than 30 percent of people covered by AMO make use of their insurance in the absence of a third-party payer system as they cannot pay for medical services and pharmaceuticals upfront, especially in the case of expensive long-term treatments. There are only about 90 expensive products which have been integrated in the third-party payer system.

When we met your predecessor Abdelmajid Belaiche in 2015, he mentioned that his priority was the acceleration of the registration procedure. What progress has been made on that front?

A decree for marketing authorizations was published in 2014 which set the timeframe to receive an answer to marketing authorization dossiers at ten months. However, the decree includes many caveats which can significantly extend this timeframe.

In addition, this decree regrettably introduced hurdles to local production as it makes it easier for imported products to receive marketing authorization compared to locally manufactured products. The price decree of 2014 also advantages imported products by granting them a 10 percent bonus.

Has access to innovative treatments improved?

There is better access to innovative biotechnological treatments through the introduction of biosimilars. The Sothema group has partnered with Russian biotechnology company BIOCAD to establish a biosimilars unit in Morocco for rituximab and bevacizumab. Today, the unit only performs fill-and-finish operations, but the company wants to be able to perform the entire production process by the end of the year.

The latest therapies arrive relatively rapidly in Morocco. The main issue is their registration in the reimbursement lists which takes a long time. The high prices of some of these therapies pose a problem even in developed countries, and even more so in countries like Morocco.

Morocco is positioning itself as a strategic gateway to Africa. In the pharmaceutical field, how do you assess the potential of the country as a decision and export hub to the African continent?

On this point, we are asking the government to put in place legislation in order to allow companies to export products that are not commercialized in Morocco, which today is prohibited by law. In that way, Moroccan companies could play a role in helping other African countries fight against infectious diseases which have been eradicated or have never existed in Morocco. Moreover, it would attract investments from foreign companies that could use Morocco as an export hub for Africa.

Despite this hurdle, what do you think makes Morocco attractive as an investment destination for foreign pharma companies?

Morocco is an attractive investment destination in the region because the country has a strategic location between Europe and Africa, strong economic fundamentals, manufacturing infrastructures on par with international standards, skilled human capital, a favorable business environment as investors are able to repatriate all their dividends, a solid financial system, and access to a market of one billion consumers with all the free trade agreements signed by Morocco.

Speaking of Morocco's role for health in Africa, AMIP is co-organizing the fifth Africa Health Business Symposium (AHBS) which will take place in Casablanca on October 22-23. What should decision-makers in the industry know about this event?

As a National Health Federation did not exist in Morocco before (it was created a few months ago), AMIP represented Morocco at the Africa Healthcare Federation (AHF) of which I am a board member, and at this symposium which is organized in a different country every year. I participated in the past three editions in Addis Ababa, Johannesburg and Dakar, and strongly advocated for the 2020 edition to be organized in Morocco. We have already received support from health authorities for the organization of this event, and we will ask for the patronage of His Majesty King Mohammed VI who is a strong advocate for South-South cooperation.

AHBS is Africa's largest health business event and promotes public-private partnerships by gathering Ministers of Health, NGOs, health federations, pharmaceutical and medical technology companies, digital health companies, and so on. This year's edition is organized under the theme "Towards Resilient & Sustainable Health Systems". In my opinion, anybody interested in finding solutions for health in Africa should participate.

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