# Aziz Mrabti – Director General, Medicines & Pharmacy Directorate (DMP), Morocco

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*General Director Dr Aziz Mrabti discusses the Moroccan Medicines & Pharmacy Directorate (DMP)'s transition to an independent regulatory authority, highlighting its potential to enhance autonomy and international recognition. He also emphasizes Morocco's commitment to supporting the growth of the healthcare and pharmaceutical sectors, both domestically and internationally, amid the generational healthcare system transformation currently underway.*

**Can you provide some insights into the historical and current functions of the DMP, aside from reform discussions? What specific responsibilities fall within its jurisdiction?**

It is worth noting that the Ministry of Health and social protection operates with a central administration comprising nine directorates, one of which is the DMP.

The structure of the Ministry of Health and social protection, particularly within our department, has been in place since 1994. The DMP was established in 1994 with its primary mission being the regulatory oversight of medicines and healthcare products in Morocco. It involves granting authorizations, regulating, supervising, and maintaining oversight over all matters concerning medicines and healthcare products in Morocco.

**Is it similar to the US FDA in terms of primarily focusing on authorizations with no input on price negotiations?**

When I mention that it serves as the regulatory authority, it begins with granting authorizations for establishments to operate in the pharmaceutical sector. For instance, if a pharmaceutical manufacturing facility wishes to establish itself in Morocco, it must obtain authorization, a process overseen by the government's General Secretariat after review of the DMP. This initial step involves authorizing the pharmaceutical industry to operate within Morocco's borders. Additionally, any pharmaceutical product seeking entry into the Moroccan market requires market authorization, known as Marketing Authorization (AMM), and it is the responsibility of the DMP to grant this approval.

Furthermore, for a pharmaceutical product to be introduced to the Moroccan market, it must not only secure market authorization but also have an assigned price. Our department, the DMP, is tasked with determining drug prices through an interministerial committee, following a strategy outlined in a decree.

**Do pharmaceutical companies request price adjustments directly from your organization, or do they initiate these requests through their clients? Additionally, could you clarify whether the prices set by the DMP undergo negotiation once established, considering they are officially determined through ministerial decrees?**

Pharmaceutical companies typically submit price adjustment requests directly to our organization. As for the prices established by the DMP, they follow a regulatory framework and are officially set through ministerial decrees, granting them legal status. While these prices are initially determined based on benchmarking and other factors with transparency, the regulatory framework allows pharmaceutical companies to request both upward and downward price adjustments after the initial establishment.

**What do you feel will be the full impact of the ongoing healthcare reform in Morocco?**

We are currently in a historic moment. Since the COVID-19 pandemic, His Majesty the King has given important instructions for a major project: social protection. In the healthcare sector, this

includes mandatory health insurance. Almost 100 percent of the Moroccan population is now covered by health insurance. This is a giant step forward and a significant achievement, especially considering that before 2015, only 16 percent of Moroccans had health insurance coverage.

When we talk about health insurance, the most important thing is allowing the Moroccan population to access healthcare, medicines, and healthcare products without financial barriers.

To succeed in this, it is not enough to say that we've achieved 100 percent coverage; we need to make it sustainable. The Ministry of Health and social protection  has introduced a major reform, and this is the first time we have seen such a profound transformation since the creation of our healthcare system.

There are four key levers. The first one, which is critical, is governance, involving the creation of new governance bodies such as the Drug Agency. The second lever concerns human resources which are considered the drivers of any reform. They need to be revalued, and their status should be attractive. This has been done and continues in the second lever. The third lever relates to healthcare services. We are talking about healthcare coverage and mandatory health insurance, but we also need to ensure that the services are available. The fourth lever concerns information systems and digitization. Digitization is essential for progress and accessing information.

One crucial development that will significantly impact the quality of care and patient management in our healthcare facilities is the implementation of an electronic medical record shared across the system. This will greatly facilitate the patient's care journey within our system and provide all the necessary information for sound decision-making. These two elements form the roadmap that will reorganize our healthcare system, which is particularly important.

**How would you characterise pharmaceutical policy in Morocco today?**

In Morocco, our pharmaceutical policy is guided by a visionary leader, His Majesty the King. While Morocco had a national pharmaceutical policy for 2015-2020, His Majesty's directives and changing priorities have led us to finalize and publish, before the end of this year, a new national pharmaceutical policy for 2023-2027. This policy serves as the official document for the entire government, outlining fundamental aspects of the pharmaceutical sector in Morocco. It presents critical levers, specific actions, precise timelines, and dedicated financing to ensure national sovereignty, promote the national pharmaceutical industry's development, support other healthcare product sectors, and ensure the availability of quality and affordable medicines and

healthcare products to the Moroccan population.

**Looking at timing and quality. For instance, when you receive a laboratory dossier, approximately how long does it take in Morocco to obtain market authorization? And is this authorization provided along with established prices, or is pricing a separate step?**

I want to emphasize that the pharmaceutical sector in Morocco is well-regulated. We have had regulations in place for over 70 years, and while they have evolved, they provide a solid framework for the pharmaceutical sector. There is a specific decree regarding market authorization, which stipulates a total of 10 months for the reference drug (originator) and nine months for generic drugs. Within these timelines, there are various stages and deadlines in place for administrative responses and the responsiveness of the pharmaceutical establishment. We make every effort to strictly adhere to the different stages and deadlines. However, if we encounter delays, which may occur due to issues on the part of either the industry or the administration, we try to manage them through collaboration.

**In some countries, a lack of response implies approval, allowing the manufacturer to market their product. Is that not the case here?**

First and foremost, market authorization is mandatory. After obtaining market authorization, pharmaceutical companies can initiate the pricing request process. It is essential to establish the quality, safety, and efficacy of the drug before discussing pricing matters. Once the market authorization is secured, they can proceed with pricing applications, and these negotiations take place within the appropriate committee. Usually, we hold an average of one committee meeting per month, but if there is a substantial influx of requests, we may convene up to two meetings in a month.

**Some of the Middle East and Africa’s leading countries have implemented a policy where they grant direct approval to dossiers evaluated by gold standard regulators like the EMA or the US FDA. Is Morocco contemplating a similar strategy, or does it prioritize its sovereignty and pharmaceutical policy over such an approach?**

Morocco, while having well-established regulatory timelines mandated by law, approaches this matter within the context of our national pharmaceutical policy and strategic directives. Our responses are tailored to specific national needs under the guidance of the Minister of Health and social protection. While we highly prioritize adherence to regulations, we are actively developing a fast-track approach for essential medicines to address critical healthcare needs swiftly. Simultaneously, we are committed to promoting local production as the basis of our national sovereignty efforts.

**Morocco boasts a significant number of laboratories, which sets it apart from many of its neighbours. However, most of their production centres around generic medicines, often with low price points. Does this hinder these laboratories from venturing into the development of more advanced pharmaceuticals?**

Certainly, as you mentioned, the pharmaceutical sector in Morocco comprises 56 pharmaceutical industrial establishments, 66 wholesale distributors, and an extensive network of over 11,500 community pharmacies. These pharmacies serve as the main distribution circuit for medicines in Morocco, in addition to public health facilities, clinics, and similar institutions. Among the 56 pharmaceutical industrial establishments, we have a mix of Moroccan producers and multinational companies operating in the country. Morocco, with its open approach, aims to facilitate and encourage the growth of major players in the pharmaceutical sector within its borders.

**While medicinal sovereignty is an admirable goal, realistically global biopharma cannot place manufacturing facilities in every country in which it markets its drugs, meaning that developing economies like Morocco must continue to rely on imports for many advanced therapies. What is your approach to this issue?**

We have been cultivating our pharmaceutical ecosystem in Morocco for over seven decades in collaboration with Moroccan and multinational stakeholders. A distinctive feature of Moroccan regulations is the requirement for pharmaceutical industrial establishments to produce locally to operate and establish themselves in Morocco. This requirement has been foundational. Even multinational companies operating in Morocco engage in local production, underscoring its significance.

The pharmaceutical ecosystem we have cultivated allows us to meet over 70 percent of our local pharmaceutical requirements, a substantial achievement, and we aim to raise this percentage further. We currently have over 7,500 registered pharmaceutical products in Morocco, spanning a wide array of therapeutic categories, from common to highly specialized treatments. Consequently, we boast extensive coverage and product availability, encompassing not only conventional pharmaceuticals but also innovative medications, immuno-oncology treatments, and biotechnology-derived drugs.

Morocco has initiated the local production of these innovative medications, especially following the COVID-19 crisis and royal directives aimed at safeguarding national sovereignty. Morocco is actively championing the advancement of these sectors. It is important to emphasize that this endeavour extends beyond the Ministry of Health; it involves the entire Moroccan government, which is dedicated to facilitating success and offering the necessary tools to all stakeholders. Presently, Morocco stands as an appealing investment destination, owing to its numerous merits, including stability, strategic geographic location (a mere 14 kilometres from Europe), and its pivotal role as the gateway to Africa, one of the world’s largest international markets. Investors are met with a host of advantages. Moreover, there exists a concerted effort and policy alignments to reinforce sector development and encourage investment in Morocco.

Hence, regarding the national pharmaceutical policy, fostering innovation, promoting the local production of innovative products, and supporting biomedical research constitute pivotal facets. We have allocated important resources to ensure their growth and prosperity.

**Are there plans to enact new legislation that fosters greater flexibility in importing advanced, innovative products without triggering local production agreements?**

The vision and strategic direction in Morocco are quite clear. Firstly, it is crucial to note that major global multinational pharmaceutical companies are actively present and represented in Morocco, which holds significant importance. Secondly, in terms of medicines, once marketing authorization is granted, it can be either for local manufacturing or importation. In essence, from the outset, each pharmaceutical industrial establishment knows the status of its product, whether it is intended for importation or local production. Naturally, there is an established mechanism for companies wishing to transition from importation to local production, subject to specific conditions. Conversely, there are conditions for products transitioning from local production to importation. In general, the importation status exists and will continue to exist.

However, our primary focus is on supporting stakeholders in achieving local production. This is our overarching goal, and we are actively working on initiatives such as technology transfer and more. I would like to highlight a significant project inaugurated by His Majesty the King, the local production of the Marbio vaccine. This project is of immense magnitude and embodies national sovereignty in the realm of vaccines. Morocco is now poised to produce advanced vaccines, including technology transfer, not only for its own use but also for the African continent and beyond. Morocco owns the capability for technology transfer and the implementation of local manufacturing projects incorporating cutting-edge technologies.

**What can we expect in terms of changes to the operations of the DMP? Will it essentially remain the same but with enhanced planning tools thanks to digitization, or are there more fundamental shifts in your working processes?**

This transformation will, at its core, reshape the structure and standing of our directorate. Currently, we function as a central directorate within the Ministry of Health and social protection. However, in the near future, we will go through a transformation into a public establishment with its own legal personality and financial autonomy. This transformation is of immense importance, as it will grant greater autonomy upon our regulatory authority. This newfound autonomy is pivotal and highly advantageous for our sector. It will enable us to operate with more efficiency and confidence when engaging with international stakeholders.

Under this new status, we will have the capacity to collaborate with major international agencies. One of the most impactful aspects of regulatory timelines is the potential for mutual recognition between the Moroccan agency and other regulatory bodies. This can guide us to significant reductions in the timelines for medicines that have already been registered or overseen by other regulatory agencies. Consequently, this transformation is profoundly significant.

Additionally, as part of this transformation, we are in the process of establishing a dedicated structure within our directorate that will support the agency in facilitating the development of our sector. Our directorate will no longer solely function as a regulatory body but will also serve as a catalyst for the sector’s growth. This concept of supporting development, fostering local production, promoting exports, and more is fundamental. Another facet to consider is that, since the constitution of our directorate, our primary focus has been on medicines. However, another sector is rapidly burgeoning and holds equal importance—the healthcare products sector. When we refer to healthcare products, we encompass medical devices, dietary supplements, reagents, and

related items. This is another sector experiencing rapid growth, and our agency will play a critical role in its regulation and oversight.

**Do you have plans to pursue membership of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) or seek other internationally recognised labels for Morocco's regulator?**

The directorate already enjoys a prominent international standing, with our national drug testing laboratory having garnered international recognition. It has earned recognition from the World Health Organization (WHO) and holds accreditation from the European Directorate for the Quality of Medicines (EDQM). The quality of Moroccan medicines enjoys global recognition, and our pharmaceutical products are exported worldwide, spanning Europe, Asia, Africa, and beyond. However, enhancing the agency's international positioning is of great significance, and the new agency status will allow us to achieve precisely that. We will actively pursue international recognition and strive to bring the agency's standards in line with international benchmarks. This stands as one of our key objectives and aligns seamlessly with our national pharmaceutical policy.

**What is your take on the significance of the African Medicines Agency, set to be headquartered in Rwanda, and what contributions or influences do you envision a country like Morocco, with substantial experience in the sector, could bring to its establishment and functioning?**

Firstly, the Moroccan pharmaceutical industry is the second largest in Africa. Morocco holds an essential role, particularly in the pharmaceutical sector, known for its high-quality medicines with international recognition. In alignment with Morocco's African-focused policies, we consider our nation a vital contributor, especially in the pharmaceutical domain. We take pride in being among the few countries with such robust local production capabilities, exporting Moroccan medicines to numerous African nations.

Regarding the African Medicines Agency, Morocco has been a proactive advocate of its establishment since the outset. We view this initiative as highly significant because it aims to coordinate and consolidate efforts for progress. Morocco places great emphasis on the success of this project, currently based in the neighbouring and friendly nation of Rwanda. Morocco actively participates in this initiative, committing substantial resources and expertise to ensure its

prosperous realization. We firmly believe in its potential to positively impact the pharmaceutical sector across Africa, chiefly by facilitating access to quality and affordable medicines for the African population, a crucial goal we completely support.

**As we look ahead, what do you see as the main challenges on the horizon as Morocco continues this overarching reform of its healthcare and pharmaceutical system?**

One significant point to emphasize is that Morocco is currently undergoing profound and far-reaching transformations. These transformations have created considerable opportunities in the realms of healthcare coverage and pharmaceuticals. The main goal is to foster a beneficial environment for investment, particularly within the healthcare sector. I urge all stakeholders to seize this momentous opportunity. There are numerous facets to leverage and gain from during this pivotal transformation of our healthcare system. The ongoing changes in the sector will not only have a positive impact on healthcare and medication accessibility for the Moroccan population but will also extend to African populations and other nations that utilize Moroccan products manufactured here.

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