Mariam Al Jalahma – CEO, National Health Regulatory Authority (NHRA), Kingdom of Bahrain

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Dr Mariam Al Jalahma, CEO of the Kingdom of Bahrain's National Health Regulatory Authority (NHRA) remarks on the healthcare transformation that led to the creation of the NHRA and explains the Bahraini regulatory body's comprehensive responsibilities that range from the registration and pricing of essential medicines to the approval of clinical trials.

Could you begin by introducing the country of Bahrain and its regional significance?

Bahrain is a small island in the middle of the Gulf Sea with a population of 1.6 million and has always been at the heart of regional trade. Historically, the country is well known for its natural pearl production and has long been a leader in terms of education – especially the education of women – in this part of the world, even before oil was discovered. Our national leadership, under Crown Prince and Prime Minister Salman bin Hamad Al Khalifa, has worked tirelessly to enhance the role of women within Bahraini society.

Bahrain has a very open market that is conducive to all types of international investment, including in the medical field. The investment arm of the government subsidises medical device investment by up to 40 percent as well as subsidising the salaries of employed Bahrainis by 70 percent in the first year, 50 percent in the second year, and 30 percent in the third.

What is the overall level of healthcare provision in Bahrain and how widespread is universal healthcare?

Bahrain, as per its constitution, provides free universal healthcare to all its citizens. The country boasts a network of primary healthcare centres which act as gatekeepers, managing healthcare for all citizens, and referring the 10 percent of patients that require secondary care to secondary care hospitals. There are three major public hospitals in Bahrain – Salmaniya Medical Complex in Salmaniya, Bahrain Royal Medical Services in Riffa, and King Hamad University Hospital in Busaiteen – as well as a network of private sector hospitals.

In addition to providing free care to Bahrainis, the country is now moving towards implementing national health insurance to ensure universal health coverage for non-nationals as well. Bahrainis will continue to be covered by the public sector as well as being able to utilise private sector facilities, while all working foreigners will be mandated to be insured by their employer, or if they are self-employed, by themselves.

What was the philosophy behind the founding of the National Health Regulatory Authority (NHRA)?

Bahrain’s healthcare system has changed tremendously over the past decade. Prior to 2009, one small office within the Ministry of Health oversaw the entire provision and regulation of the healthcare sector, but via a Royal Decree and the rollout of our Vision 2030 economic transformation plan, an independent regulatory body – The NHRA – was established. Since then, the NHRA has taken control of all the regulatory procedures and control within healthcare, from the licensing of hospitals to the licensing of professionals working in those hospitals, the licensing and registration of medicines and medical devices, clinical trials, accreditation for the healthcare facilities, investigating medical errors, and disciplinary actions. The NHRA is a unique agency within the region in that all these functions are under one roof.

We are overseen by the Bahraini Supreme Council of Health which puts strategies and policies in place. The Ministry of Health provides public health, while hospitals and primary care institutions work under a board of trustees.

National regulatory bodies have varying roles depending on the countries in which they sit. How does the Bahraini NHRA differ from its equivalents in other geographies? Does it, like the Saudi Food & Drug Authority (Saudi FDA) but unlike the US Food & Drug Administration (US FDA) and the European Medicines Agency (EMA), have a pricing mandate?

The NHRA oversees and licenses all healthcare facilities and healthcare professionals (HCPs) in Bahrain. This includes classifying HCPs by their qualification levels and licensing them accordingly, investigating issues within facilities, and conducting both unannounced and routine inspections.

In terms of medication, we are responsible for both the registration and pricing of essential medicines. For pricing, we follow the unified price set by the Gulf Cooperation Council (GCC), adding a limited profit margin of 20 to 30 percent, well within the GCC stated limit of 45 percent.

The only part of the value chain we do not cover is purchasing, which is conducted by the public and private sectors themselves. We only give approval to register and import medication.

The NHRA also regulates medical devices, although does not have a pricing mandate there. Instead, we ensure that medical device companies follow certain standards, implement proper systems, and have the correct certifications for the products they are importing.

Our mandate does not extend to food and food supplements, which are controlled by the Ministry of Health.

Additionally, the NHRA is charged with accrediting facilities and has a dedicated team of surveyors who evaluate hospital performance and give certifications every four years.

We also approve clinical trials that are conducted in Bahrain, including a significant recent trial of the Sinopharm COVID-19 vaccine, which was eventually approved for use in the country.

Finally, we investigate medical errors and claims.

To what extent does the NHRA leverage the regulatory work done by the US FDA or EMA?

This process is important to us, especially for manufacturing sites. If a site already has a GMP certificate from the WHO, US FDA, EMA, or Saudi FDA, or indeed if it has been registered by the GCC, we do not have to conduct inspections ourselves. For alternative medicine or traditional

medicine manufacturing sites – which we also oversee – global regulatory inspections are not necessary.

Globally, more and more new highly priced and specialised medicines are coming onto the market. As a regulator how do you approach budgetary concerns?

As mentioned, we price medication based on the unified price agreed across the GCC, but of course our government is looking at how to reduce spending, including via generification.

Bahrain has a drug committee that decides which drugs are introduced to the public system, but of course the private market is open. The NHRA controls pricing, but it is up to the citizens which medicines to buy. One issue that arises from this is patients looking in the private market for originator drugs when we have alternatives available. A misunderstanding can occur when they search for a certain originator cream or syrup, see that it has been discontinued, and erroneously assume that there is a shortage. For that reason, we openly publish a list of registered drugs on our web page with the generic name, the agent name, and the pricing, all of which is made available to the public.

However, we know that there are some needs for medications that are not registered. Therefore, to increase flexibility, the Supreme Council of Health has issued a resolution (Resolution 21) that allows some non-NHRA-registered medications to enter the Bahraini market if they are US FDA or EMA approved. This sometimes occurs for orphan drugs or highly specialised oncology treatments.

Also on the flexibility point, when an agent submits a registration dossier, they are able to immediately begin importing and marketing during the six months to one year it takes to fully register the product.

How would you characterise the NHRA's and Bahrain's response to the COVID-19 pandemic?

Prime Minister bin Hamad and his team rapidly assembled a national taskforce to counter the disease back in 2020, and our national response has been cited as a true success story by the WHO. The NHRA is an important member of this taskforce, working to accelerate the approvals of medicines and medical supplies, as well as grant emergency use authorisations (EUAs) for vaccines during the pandemic. Today, seven vaccines have received EUAs in Bahrain, giving our citizens a

great amount of choice.

We also worked to grant EUAs to the myriad rapid antigen tests that were developed during this period, coordinating with other public health sector stakeholders to make comparisons with PCR testing and guaranteeing their quality.

Furthermore, we reduced some of the requirements for HCPs, including the obligation of continuing professional training in order to renew medical licenses, as training programs were not possible during this period.

Another key item was permitting pharmacies to conduct rapid antigen tests and issue certificates. Saudi Arabia, with which we are connected by the King Fahd Causeway, required these tests for those entering the country and a large number of people move between the two nations on a daily and weekly basis.

We licensed the private sectors to conduct the PCR tests, operate hotels as quarantine and isolation facilities, and even allow company buildings to perform such functions providing they are supervised by a medical facility. This was especially relevant for the large number of migrant workers we have in Bahrain.

Overall, the Bahraini public and private sectors worked together very well against COVID-19, collaborating to solve complex problems and reacting quickly to a dynamic and challenging environment.

The NHRA took the decision to approve the Chinese Sinopharm vaccine, while the US FDA and EMA did not; what was the thinking behind this decision?

In an environment of intense competition to secure vaccines for domestic populations, the Bahrain government made the pragmatic decision to secure the first vaccine we were able to, which turned out to be the Sinopharm product. In collaboration with UAE, we conducted a large-scale study, including an in-country Phase III clinical trial of 7,700 citizens in which even our Prime Minister participated, to gauge the vaccine’s safety and effectiveness.

This first approval was then followed by EUAs for the Pfizer/BioNtech, AstraZeneca, Sputnik V, and Valneva vaccines based on a rolling submission mechanism, whereby the sponsors continue to submit data post-EUA.

Some countries have sponsored certain patients to travel abroad to receive advanced therapies not approved or available in their own country. Is this something that Bahrain is considering? What is the NHRA's approach to advanced therapies more generally?

Patients in Bahrain are able to access NHRA-approved therapies in-country and our overseas committee will only sponsor patients to go abroad to receive a treatment that has received full regulatory approval. In other words, Bahrain does not sponsor citizens' participation in clinical trial studies abroad.

Within Bahrain, we are developing our understanding of stem cell therapy through the regenerative medicine program at Arabian Gulf University and research on diabetes at the Royal College of Surgeons in Ireland – Bahrain, with legislation on the use of stem cells in treatment to come soon.

Stem cell therapies already approved by the US FDA or EMA will be granted use in Bahrain, but we must ensure to define what stem cell therapy actually is and not be swayed by commercial arguments.

Is Bahrain prioritising investment in science and what role do you see for the NHRA in incentivising further investment?

The NHRA strongly supports local manufacturers, of which we currently have two based on Bahraini-Saudi investments. One is working on injectables and the other on food supplements. Many more investors are visiting Bahrain to explore the opportunities here and the government agency Tamkeen is subsidising many of the processes around issues like staffing and IT support. Moreover, Bahrain's Economic Development Board connects investors with opportunities, either with government or the private sector.

Two years back, the NHRA opened its own investors office. Located in the reception of our building, our officers guide potential investors on the requirements needed and the support available to invest in Bahrain in anything from high-tech robotics to traditional medicine.

What message would you like to pass to our global audience about Bahrain and the GCC more generally?

Uniquely, the GCC has a central registration mechanism meaning that manufacturers can register their site and medications at the GCC office in Riyadh before entering tenders for the entire unified

GCC purchasing mechanism. Instead of entering one country, sponsor companies can therefore enter six.

This kind of harmonisation is incredibly helpful to all stakeholders. Regulatory harmonisation makes the exchange of information easier, allows companies to register their medicines more straightforwardly in more countries without having to duplicate processes, and also eases the process of post-authorisation pharmacovigilance.

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