Hisham Bin Saad Al-Jadhey – CEO, Saudi Food and Drug Authority (SFDA)

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Speaking exclusively to PharmaBoardroom, Prof. Hisham Bin Saad Al-Jadhey, CEO of the Saudi Food and Drug Authority (SFDA), outlines the SFDA's key priorities under its current strategic plan. He also touches on why domestic pharma and medtech manufacturing is important to the SFDA, pricing issues for innovative new therapies, and the role of the Authority within the Saudi 'Vision 2030' plan.

Hisham, could you start by introducing the mandate and mission of the Saudi Food and Drug Authority (SFDA), since the role of the regulator differs across countries?

In Saudi Arabia, the regulator – the Saudi Food and Drug Authority (SFDA) – looks at any product that affects health, in direct and indirect ways. Having done a global benchmark, we know that compared to other regulators in the world, we have one of the largest mandates, since we cover food, drugs, medical devices, and even agricultural products like animal feed and pesticides, as well as cosmetics.

Our mission is to protect public health and improve its quality while fostering trade and investment across the sectors we cover. To do this, we have regulations and standards that we apply on products both manufactured in, and imported into, Saudi Arabia. As a result, we are also responsible for the border control and inspection in the areas that we cover. We are directly

present in over 16 air, land, and seaports across the country, and in other ports we are also available remotely. We work with other governmental entities to perform such inspections.

This is significant since many regulators do not have such border responsibilities, and it is a huge undertaking. For instance, Saudi Arabia imports over 80 percent of our food from over 157 countries. This has exposed us to many different aspects of food safety as well as many different country practices. We have to ensure that importers understand and comply with our regulations to ensure that only safe products enter the country. This takes a lot of time and effort.

Overall, we have over 2,100 employees. We are working to improve the efficiency of the authority. We have a strategic plan and many incentives to be one of the top science-based authorities in the world.

With such diverse responsibilities, how is the SFDA structured?

SFDA was established around 17 years ago. In that time, we have had three strategic plans, with the third and current one ending in 2022. During most of that time, the vision was for the SFDA to be a leading regulator in the region, but we updated this vision four years ago because we realized we had already achieved leadership within the region. Now, we are advancing towards international leadership, and based on this, we have updated our strategy, work priorities and structure.

Four years ago, we separated a number of positions to increase the efficiency of the organization. We have a team that manages operations, i.e., border inspections, some products registration, and inspection of manufacturing plants, establishments licensing. A separate team function as scientists and evaluators for the different categories of products that we regulate. A third team focuses on the research and laboratory work, again, for the different product categories. A few years ago, for instance, we established a reference laboratory for food, and we are now promoting to the private sector to manage the day-to-day analysis while we will only look at the reference samples.

Can you highlight some of the major priorities under your ongoing strategic plan?

Our third strategic plan has really focused on defining and setting Key Performance Indicators (KPIs) for our objectives. For instance, one of our KPIs is in the reduction of foodborne illnesses. The

goal was to decrease it by ten percent, and we have achieved this. In fact, as a result of COVID-19, we actually saw a reduction of over 50 percent in part due to the increase in hygiene practices people have implemented. This is an area where we are also working with other government entities, the private sector, and individuals, to improve.

We have similar KPIs for medicines and medical devices as well to help us bridge the gap between where we are and where we want to be. For example, in terms of clinical trials, we currently have clinical trials in the country and we approve them, but there are some challenges when it comes to their operations. We want to highlight Saudi Arabia as a unique clinical trial destination.

Another priority has been to strengthen our capabilities. In food, as an example, we more than doubled the size of our risk assessment team in the last three years, not only that but we are also focusing on enhancing the quality of the talents in our team by hiring employees with high education degrees to advance the quality of work.

In addition, we have signed many different Memorandums of Understanding (MoUs) to improve our capacity. For instance, we assembled an international advisory board including some former heads of other regulatory agencies to advise our risk assessment team.

We did the same for the drugs and medical devices teams. For instance, we have doubled the number of evaluators we have, from around 70 four years ago to over 150 evaluators now. We also have around 50 scientists working on the regulatory science side. We initiated a new quality check program, where we bring in international consultants to review our evaluation, which offer learning opportunities for our team.

We are investing a lot in developing our regulatory capabilities, especially for drugs. We know that biologics has become a hugely important area and it is the future of medicine, so in 2017, we established a new biologics department within the SFDA.

We have also embraced collaborations with universities across Saudi Arabia, and we hope to establish reference laboratories for different projects in these universities.

Communication is another very important priority for us. Our aim is to be the leading source of reliable and important communication about the benefits and safety concerns of food, drugs and medical devices in the world – mainly in Arabic. There are a lot of Arabic speakers, even in non-Arabic countries, and we want to provide them with the right information. For instance, we have started a project to create a video on this topic that can be seen by 1 billion people in the world. We have around 100 volunteers working on this right now.

Another really important priority is international collaboration. We have around 14 MOUs signed with different countries, and we are also participating actively in international organizations. For instance, we led the global harmonization working group for medical devices and we are part of the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use (ICH). We lead the Near East Committee for the Codex Alimentarius, a collection of international food standards set by the Food and Agriculture Organization (FAO) of the United Nations and the World Health Organization. We have also established a new forum for food standards in collaboration with the food authorities in Australia and Ireland, which aims at gathering heads of distinctive food agencies around the world to discuss and promote public health and food safety. The first forum was held in Riyadh in January 2020, and the forum now has many members and observers such as the US, France, South Korea, Japan, China, Kuwait and Morocco. Also, many international organizations have joined the forum as observers such as WHO, the FAO and the Codex.

Two years ago, we also established the National Committee on Nutrition, which is part of SFDA and which I chair. We have a number of governmental and private committee members, and they meet very actively. The goal is to improve the nutrition of people in Saudi Arabia. We have invested tens of millions of riyals to conduct studies regarding the nutritional status and needs of the Saudi people because we currently only have figures from external sources. We do not know how many calories Saudi people actually need. We do not know their current daily consumption. We want to conduct these studies and update the nutritional recommendations for Saudi people.

Last but not least, we are working on projects to promote HALAL products and regulations. The SFDA now has a Saudi HALAL Center, which issues HALAL certifications. I am leading our strategic work here on a national level. We meet every two weeks with over 16 governmental entities, including the Ministry of Industry and Mineral Resources and the Saudi Export Development Authority We will also organize the HALAL Expo this year. We are developing a halal hub in King Abdullah Economic City. These efforts relate to our focus on nutrition and healthy food, because we want to personalize the halal diet and recommendations for each individual, right down to the source of the animal feed.

As you mentioned, the SFDA is already the leading and reference regulator for the region, and part of that has to do with the market size, exposure to new technology and therapies, and the regulator’s own capabilities. To what extent is it important to SFDA to support more pharma and medtech manufacturing in Saudi Arabia?

This is a very important point. We have the largest drug and medical device market in the Middle East and North Africa (MENA) but in terms of domestic manufacturing and industry size, we are still behind not only the Western countries but also many Asian countries. This has impacted us, for instance, in terms of the availability of medication. Having a strong domestic industry, not just in terms of generics but also innovative therapies and R&D, also helps us since it encourages us to become better. For instance, if a Saudi Arabian company develops a COVID-19 vaccine, naturally, we would be the first regulator to approve that vaccine, and we would need to develop very strong regulatory processes to do that, which helps us grow.
We have certainly worked for years to develop our capabilities, and the government has invested significantly in the sector, which has helped to raise the level of the industry. The industry and the regulator can grow and support each other.

We also have our own pharmaceutical standards that are used by other countries within the region. The Gulf Cooperation Council (GCC) countries have a unified GCC Health Council for the registration of medicines and we are the leading regulator in this region.

With the wave of new therapies in areas like oncology and rare diseases, how is the SFDA supporting the deployment of these therapies in the country?

CAR-T therapies have already been approved in Saudi Arabia. We have very advanced hospitals that are working with these therapies and we have the regulation in place. For instance, we are working with King Faisal Specialist Hospital & Research Center to use these treatments,

There are also plans for Riyadh to become a center for healthcare and health tourism within the region. The availability and safety of medications, as well as the robustness of the regulatory process, are very important enablers for these plans to succeed so we have an important role to play.

We also want to support companies to manufacture CAR-T therapies locally, so we are investing in the regulation and talent ecosystem around this.

The SFDA also has a pricing mandate for therapies and medical devices. What is your general perspective on the challenges of pricing, and especially given the expensive price tags of the new cell and gene therapies, during a time of COVID-19 where resources also have to be dedicated to pandemic response efforts?

Drug pricing is a difficult issue for almost every country in the world. There are basically two ways of looking at it.

The first is to leave it to the market to fix. But people generally believe that some products are essentials and they should be affordable for everyone. These products are bread, water, and medicine. People generally think the government should play a role in keeping the prices of these products down. In the US, for instance, drug prices are not controlled centrally and they face a lot of affordability challenges.

The second is to understand that controlling drug prices will affect the industry investment. The US justifies their high prices in terms of the benefits to R&D investment. It is true that the US leads the world in terms of innovative healthcare products and R&D.

Essentially, there needs to be a balance between targets for consumers and targets for investment in R&D.

Another important aspect to consider is availability. If drug prices are too low, the products may not be available. For patients, the most important factor in medicines or devices is quality. The second is availability. Pricing is only the third factor.

Moving forward, as you said, the SFDA is already the gold standard regulator for the region. Saudi Arabia as a country has set out a transformational and ambitious vision for the country, Vision 2030, and healthcare is a very important pillar in this Vision. What is the role of Saudi FDA within this national plan?

We want to protect people without harming businesses and investments. Therefore, there are two dimensions. The first is in the quality of life and health. We have a lot on our plate, as I highlighted to you. Food is one of the basic sources for improving one’s health, so we are working on initiatives such as preventing the use of hydrogenated oils and reducing the use of salt, sugar and saturated fat in food. From a health point of view, the mission is to ensure that no harm results to any individual in Saudi Arabia from any food, drug or medical device. On this, we are working on initiatives such as setting up a channel for people to report adverse drug effects and strengthening our inspection activities.

The second is in investment and tourism. Put simply, tourists want to visit countries with good healthcare systems where safe and fresh food is available. Investors want to put their money in countries where there are strong regulations to protect their businesses and assets. We think we

can double, if not triple, the manufacturing and investments in Saudi Arabia, and this is what we are working towards.

I mentioned halal products as being one of our priority topics at the SFDA. I think Saudi Arabia has a strong position as the center of the Islamic world because Mecca, the holiest city in Islam, is located in our country. We can leverage this to advance our efforts in halal we want to develop standardized regulations and conventions for halal products globally, which will contribute to the halal space globally while also bringing more investments to Saudi Arabia.

In fact, around six months ago, we established a new directorate for investment support and promotion, and we brought in a professional with extensive public and private sector experience to shape our efforts here.

This is the first time PharmaBoardroom is spotlighting the Saudi Arabian healthcare ecosystem. As the CEO of the SFDA, do you have a final message for our international audience of C-level healthcare executives?

SFDA has been developing very fast over the past couple of years and our future is even more promising. We are improving our regulations and processes to protect our citizens and to bring more investments to Saudi Arabia.

As a regulator, we understand the industry’s perspective as well. They hope their investments and operations will be profitable, but we also know that the revenues they make also benefit citizens and the wider ecosystem within the country, so by supporting the industry, we are also supporting our own citizens and our own country. Sometimes industry may see some of the decisions from regulators as tough decisions but in the long term, strong regulations will support industry development and also the internationalization of domestic companies.

Today, the companies that invest in Saudi Arabia can reach a large regional market because we are well-known in the region. As we continue to advance with our initiatives and our regulations strengthen, domestic and foreign companies present in Saudi Arabia will see larger and larger international markets for their products and services.

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