GCC Medical Technology Guide

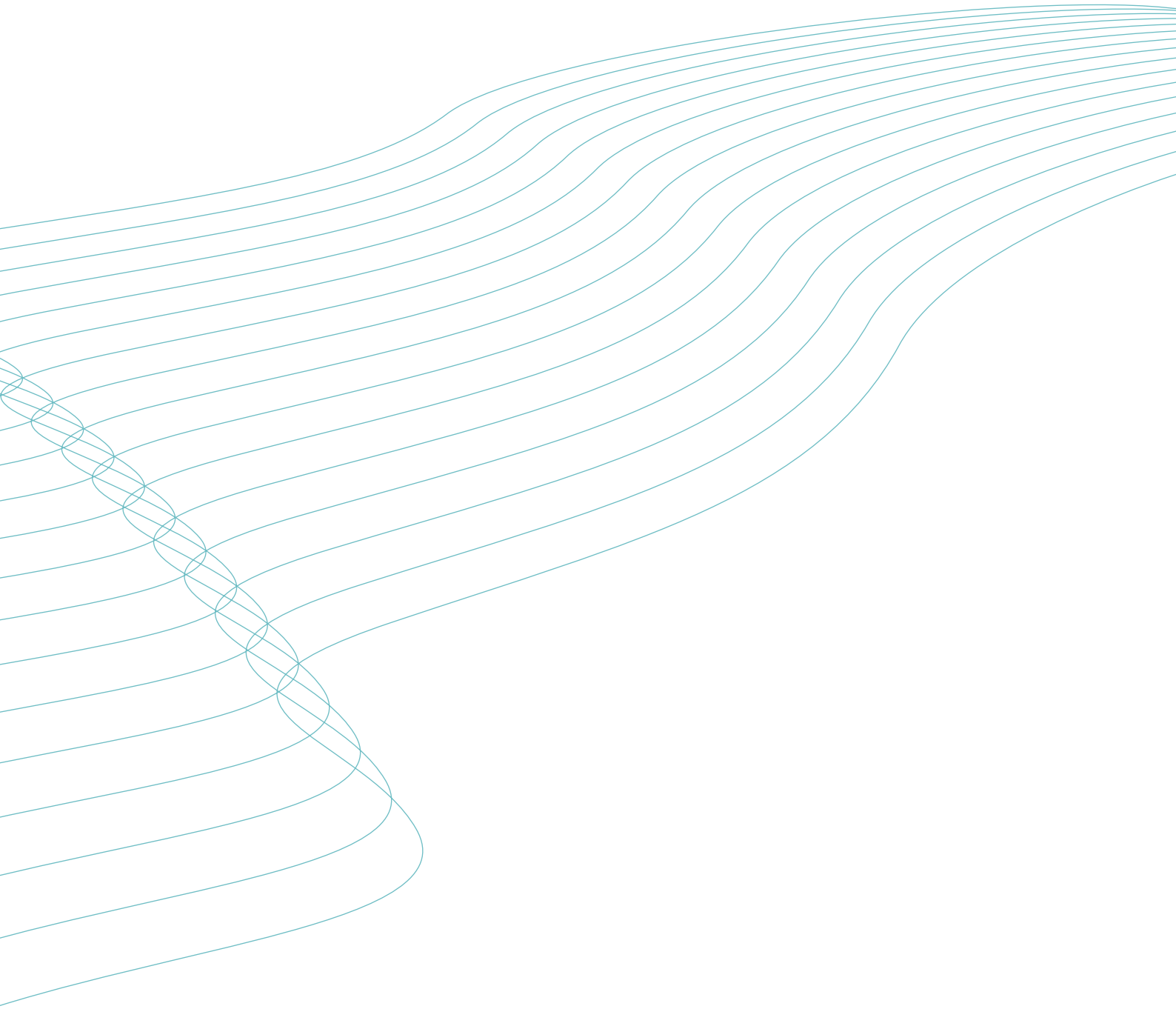
SPECTARIS
German Industry Association for Optics, Photonics, Analytical and Medical Technologies

SCHLÜTER GRAF
Passion for Law

AHK Deutsch-Emiratische Industrie- und Handelskammer
المجلس الألماني الإماراتي المشترك للصناعة و التجارة

AHK Delegation der Deutschen Wirtschaft für Saudi-Arabien, Bahrain und Jemen
German-Saudi Arabian Liaison Office for Economic Affairs (GESALO)
مكتب الاتصال الألماني السعودي للشئون الإقتصادية

This publication is a collaborative effort by the law firm SCHLÜTER GRAF Legal Consultants, the German Emirati Joint Council for Industry & Commerce (AHK) and GESALO, with the support of Spectaris.



September 2022

Preface - SCHLÜTER GRAF

Over the past decades, the GGC countries (Bahrain, Kuwait, Oman, Qatar, Saudi Arabia and the United Arab Emirates) have witnessed immense economic growth which has fueled the demand for excellent healthcare services, compelling the GCC governments to allocate a significant amount of their budgets to the healthcare sector. As a result, the region's healthcare system has witnessed a substantial boom which in return has created numerous opportunities for foreign healthcare companies to explore the healthcare market in the region.

The rapid growth in the healthcare industry in the region has led to several updates of the regulatory frameworks in the GCC countries to align them with international standards. The resulting statutory and regulatory changes as well as differing regulations in the GCC states make the highly regulated GCC healthcare sector a challenging field for foreign companies to operate in. We are therefore pleased to offer this GCC Medical Technology Guide which provides market analyses as well as overviews of the legal frameworks for the healthcare sector related to medical technology in each of the six GCC states.

Having been operating in the region since 1995, SCHLÜTER GRAF has witnessed these dynamic developments firsthand. During this period, the firm has represented and acted for the most renowned and reputable companies in the healthcare industry on the entire spectrum of healthcare laws in the GCC region. With a specific focus on the healthcare sector, our medical laws practice has grown into a highly respected and well-reputed practice in the region.

We thank our co-authors, the German Saudi Arabian Liaison Office for Economic Affairs (GESALO) and the German Emirati Joint Council for Industry & Commerce (AHK), for their valuable contributions to this publication in the market analysis sections. We furthermore would like to thank Spectaris for providing their kind support to this publication.

While the market analyses often relate to figures that are relevant to the respective German-GCC trade relations, this publication is not only intended for German healthcare companies. The legal framework sections apply to all companies doing or planning to do business in the healthcare sector in the GCC.

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Partner, SCHLÜTER GRAF

Preface - German Emirati Joint Council for Industry and Commerce & German-Saudi Arabian Liaison Office for Economic Affairs

Tremendous developments in the GCC healthcare sector continue to offer opportunities for German healthcare providers. Enjoying an excellent reputation, the GCC region has been a loyal customer of German healthcare service providers, clinics, and doctors for a long time.

Embarking on this relationship, the Gulf Region is very receptive to German knowhow and technology, especially with regards to the ambitious plans, for instance, in Saudi Arabia and the United Arab Emirates. Both countries are developing world-class service providers and setting up a competitive and efficient healthcare system. The opportunities are manifold. Privatization programs have been kicked off, new hospitals are under construction and new institutional frameworks being set up in some of the countries around the Gulf. The developments offer further opportunities for healthcare technology providers, healthcare consultants or planners to set up the new infrastructure.

Therefore, this GCC Medical Technology Guide does not only serve as a compendium for export-oriented German SMEs. It should also be seen as an 'entrée' into a region that is welcoming to any form of German engagement on the ground, be it as a provider of 'hardware' and equipment, or with expertise and technology.

The two German Chambers (AHKs) in the region, the German Saudi Arabian Liaison Office for Economic Affairs (GESALO) and the German Emirati Joint Council for Industry & Commerce (AHK) are the door-openers for German companies venturing into the MedTech and Healthcare Industry in the GCC region.

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Preface Spectaris

The German medical technology industry – a strong partner in the GCC countries

The German medical technology industry is a high-tech sector with high levels of innovation and a strong export orientation that is characterized by small and medium-sized companies. It has established strong trading partnerships with healthcare stakeholders across the globe and profits from increased demand worldwide. By combining long-standing competencies in engineering, manufacturing and healthcare, German companies are pioneers in the development of new medical devices and services. They provide state-of-the-art products that fulfill the highest quality and safety standards in accordance with international regulations. The industry also benefits from exceptional research facilities in the different health and engineering disciplines, optimal healthcare infrastructure with internationally renowned hospitals, and excellent manufacturing standards.

Thriving SME Sector

The German medical technology sector is largely made up of small and medium-sized (SME) enterprises. 93% of all medical technology companies in Germany employ less than 250 employees. The SME-structure offers a lot of advantages for the partners: They are able to react flexible, meet a broad range of demands, and supply niche products for specialist applications. Products are tailored to suit the specialized needs of customers at home and abroad. A significant number of manufacturers' service strategies extend far beyond simple product provision. Integration into and compatibility with existing systems are key in this respect. Comprehensive after-sales provisions - including maintenance and repair services - are also part of the portfolio that sets German companies apart. The total cost of ownership (TCO) for the entire product life cycle - including servicing, inspections, maintenance, and repair - is what matters most in designing and offering state-of-the-art products.

Service Excellence in Medical Technology

It is anticipated that a growing number of companies will focus on providing digital services and solutions in the coming years. In order to enhance potential and gain long-term advantages in service, all relevant factors must be considered holistically. These include strategic focus, performance management, processes and organization, IT and enabling technologies, and change management.

SPECTARIS and the German MedTech Industry

The 1,443 German producers of medical technology which each have more than 20 employees generated overall revenues of EUR 36.4 billion in 2021. Domestic revenues were EUR 12.2 billion, with foreign revenues amounting to EUR 24.2 billion (German Federal Statistical Office/ SPECTARIS). The total workforce in the German medical devices industry sums up to about 155.000 employees in 2021.

SPECTARIS is the German industry association for the high-tech medium-sized business sector and representative body in the areas of medical technology, consumer optics, analytical, bio- and laboratory technology as well as photonics. SPECTARIS pools the interests of around 400

member-companies from Germany, associated in the four sector-specific associations. The SPECTARIS trade association for Medical Technology represents the interests of nearly 150 companies in the industrial goods and appliances sector, which are predominantly small to medium-sized companies but also some globally operating enterprises.

Opportunities in emerging markets and the GCC countries

The GCC region is amongst one of the fastest growing regions for German companies – with long-lasting partnerships on a high technological and educational level. German medical technologies exports to Saudi Arabia are the highest in the region with about EUR 225 million in 2021. The UAE approximately amounted up to about EUR 128 million in 2021 with a plus of about 5.6% compared to the previous year.

We are very happy to be a partner of this comprehensive publication, which shows the prospects and future trends of the GCC region – which is of high importance to the German medical devices manufacturers and will enable them to deliver more customer-tailored services in the region.

Contents

United Arab Emirates

A. Introduction

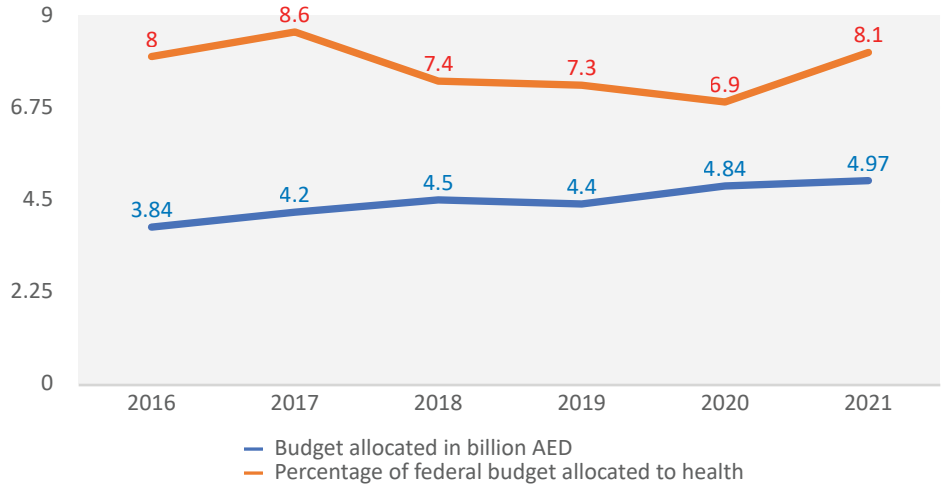
The United Arab Emirates ("**UAE**") is a federation of seven Emirates formed in 1971 which comprises of the Emirates Abu Dhabi, Ajman, Dubai, Fujairah, Ras Al Khaimah, Sharjah and Umm Al Quwain. In addition to the seven Emirates, the UAE has developed numerous free zones with distinct legal characters to attract foreign direct investment into the country. The legal and regulatory framework is divided between the federal and the Emirate levels. Overall, the legal system of the UAE is predominately a civil law system complemented by certain principles of the law derived from Islamic Sharia law.

The UAE's healthcare sector has traditionally been one of the favored sectors for foreign investors to invest in. The UAE has been predominately dependent on imports from foreign countries to fulfil its healthcare needs whether such imports are related to medical products, pharmaceuticals or healthcare facilities. The immense growth of the healthcare sector has increased the UAE's reliance on foreign investors to invest in the country's healthcare field. Factors that could contribute to the further growth and development of the healthcare sector in the UAE range from demand for better healthcare services, promotion of healthcare/medical tourism and increasing focus of the Government on primary healthcare.

B. Market Analysis: UAE

The healthcare sector of the UAE has shown tremendous growth over the past decade and will continue to be one of the UAE's fastest-growing industries in the foreseeable future. The UAE Government allocates a significant share of the federal budget to the healthcare sector every year.

I. UAE Federal and Healthcare budgets 2016 - 2021



Source: (Portal, 2016 - 2021)

An expanding population base, of which approx. 13% are over the age of 50 years at the time of writing this report, and high per capita income is fueling demand for healthcare services. Moreover, a sedentary lifestyle has increased the prevalence of high-risk diseases like diabetes and obesity (~30% of adults in the UAE are obese). A high noncommunicable diseases mortality rate of ~77% indicates increased health expenditure on the treatment of related diseases.

With the introduction of a health insurance in 2005 (Law No 23 of 2005), becoming effective in 2006, the door for provision of healthcare was also opened for private sector investors.

According to the November 2020 report by Alpen Capital, two significant trends will come into play. Firstly, since medical insurance covers for primary healthcare, capitation models like Healthcare Management offices will return to the forefront as corporates prefer cost optimization. Secondly, on a macroeconomic level, a saturation of the general clinics and hospitals will occur, and the industry will move towards specialized or super-specialty hospitals. Accordingly, more super-specialty hospitals are expected to come up in the next five years. However, with consumer behavior rapidly changing towards utilizing and requiring healthcare services, the sector is posed with the challenge to adapt to new requirements and services in line with evolving expectations.

The market may have reached a certain level of maturity in terms of the provision of general healthcare services, while future growth in niche healthcare provision (e.g., pediatrics or cardiology) is expected to be driven mainly by the private sector. Another growth factor is the goal of the UAE to become a regional center for medical tourism. Dubai and Abu Dhabi were ranked as the sixth and ninth most popular global medical tourism destinations in the world as per Medical Tourism Index 2020-2021.

The region largely depends on expatriates as healthcare professionals due to the scarcity of skilled and experienced national physicians and nurses. The lack of home-grown professionals can be partly attributed to the limited number of healthcare educational institutions in the region. Consequently, this has been one of the major factors hindering the growth of the healthcare sector.

II. Medical Devices

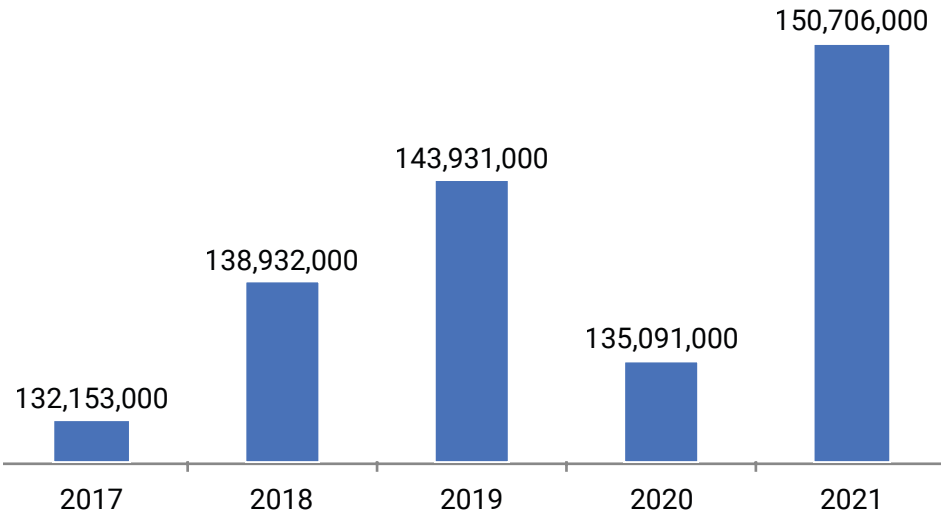
In terms of medical devices, the UAE is an import-driven market that is growing rapidly to keep pace with the country's expanding healthcare infrastructure. The government and private healthcare sector are investing heavily to provide countrywide healthcare solutions to residents, expats, and medical tourists alike.

According to BMI, the United Arab Emirates' medical device market will record single-digit CAGR growth over the 2019-2024 period, with imports supplying much of the market. It will benefit from an overall strong economic performance over the next five years, driven by a solid recovery after the significant Covid-19 dip of 2020. With rising healthcare costs, the government will increase private sector participation. Population growth, a changing epidemiology, a growing medical tourism industry, healthcare infrastructure developments, an expanding health insurance, digital transformation and new technologies will all remain key market drivers.

Germany is a main exporter of medical devices to the UAE.

III. Export Medical Devices Germany to UAE 2017 – 2021

Exports of Medical Devices from Germany to the UAE (2017 – 2021) in USD



Source: Destatis; aggregated HS Product Codes 9018, 9019, 9020, 9021, 9022.)

The recent development of German exports across the mentioned product groups shows a relatively diversified product portfolio which enjoyed growth across practically all product groups, factoring out the Covid-dip of 2020. First available figures for Q1/2 2022 indicate a double-digit export growth compared to the previous year.

According to Alpen Capital, Covid-19 has incentivized the acceleration in the healthcare curve by leveraging private sector expertise in enhancing infrastructure, deploying digitization and automation while increasing medical R&D to evolve faster. Virtual consultations, coupled with innovative solutions like telemedicine, e-ICU, remote monitoring services and online ordering of medicines have already been adopted by various operators amid the crisis.

This has not only helped diversify their offerings but also allowed a significant proportion of the primary care delivery to shift to home-based services. Such advancements have helped reduce the financial strain on healthcare systems caused by a fall in demand for elective surgeries and non-urgent care. Thus, the use of technology such as Artificial Intelligence (AI), Big Data and Machine Learning (ML) will be at the core of building new healthcare models. While this trend will be witnessed across the region, UAE will likely be at the forefront of transforming the sector. Nevertheless, improvement in current inefficiencies through better utilization of resources and capacity optimization would still remain critical while creating strategic partnerships with HealthTech/MedTech companies will pave the path for sustainable growth and overcome the challenges of living in a post-Covid-19 era.

C. Legal Framework in the UAE Healthcare Sector

I. Healthcare Legislation

The strength of any legal system lies in its ability to evolve and adapt to changing requirements of local and international business. Over the past decades, the UAE's immense economic development in the region has fueled a demand for better healthcare services which compelled the government to allocate a significant amount of its budget to the healthcare sector. As a consequence, the country's healthcare sector has seen rapid growth in the past decade. The rising demand in the healthcare sector created room to enhance the regulations of an already highly regulated sector. In this respect the UAE collectively, and Emirates such as Dubai and Abu Dhabi individually, have revamped their legal framework with regard to the healthcare sector to keep it abreast with the international standards.

In an overhaul of the legal regime in the healthcare sector, on 19 December 2019, the UAE government promulgated Federal Law No. 8 of 2019 on medical Products, Pharmacy Profession and Pharmaceutical Establishments ("**Healthcare Law**") which effectively abolished and replaced Federal Law No. 4 of 1983 on the Pharmacy Professionals and Pharmaceutical Establishments and Federal Law No. 20 of 1995 on the Drugs and Products. The Healthcare Law is a comprehensive piece of legislation which has consolidated major healthcare laws in the country and applies to medicines, medical devices and other health-related consumer goods. The Healthcare Law has an extensive scope which covers the entire spectrum of healthcare-related activities ranging from product registration and licensing to the post-market surveillance. The relevant Implementing Regulations to the Healthcare Law, Cabinet Decision No. 90 of 2021, entered into force in September 2021 to further specify the details of the Healthcare Law ("**Implementing Regulations**").

The UAE government through the Healthcare Law has introduced numerous novel concepts which clearly reflect the government's intention to introduce international standards. In this regard, a requirement on the companies has been imposed to appoint one or more qualified persons who are residing in the UAE and are licensed by the UAE authorities. This is a welcome change as it calls for direct accountability of the companies and minimizes the traditional role of agents/distributors.

In a further move to liberalize the business environment in the healthcare sector companies are now able to appoint more than one distributor for the distribution of their products in the UAE, hence, departing from a previous exclusive role of a single distributor which at times

turned out to be problematic.

In a series of changes and in order to align its legal regime in the healthcare sector with the rising role of technology in the healthcare industry, the UAE government in 2019 enacted Federal Law No. 2 of 2019 concerning the use of Information and Communication Technology in the Area of Health ("**ICT Law**"). In line with the ever-increasing digitalization in the healthcare industry, the ICT Law requires companies operating in the country to adhere to the standards set by the authorities for the confidentiality and control of electronic records of patients. Additionally, health authorities are mandated to maintain health record storage systems. Furthermore, the ICT Law bars the transfer of the patient health data outside the country without the permission of the health authority. The ICT Law has also put an extra responsibility on the businesses operating in the sector to abide by the data protection measures vigilantly.

II. Regulatory Authorities

In the UAE, the healthcare sector is regulated at both the federal and emirate levels. The primary responsibility to regulate the healthcare sector lies with the Federal Ministry of Health and Prevention ("**MOHAP**") which oversees the provision of healthcare services to the citizens and residents as per the government's policy. MOHAP also collaborates with the authorities established at the emirate level to ensure smooth functioning of the sector as per international quality standards of medical services and products. In addition to MOHAP, the emirates of Abu Dhabi, Dubai and Sharjah have formed their own health authorities which are the Department of Health ("**DOH**"), the Dubai Health Authority ("**DHA**") and the Sharjah Health Authority, respectively. Whereas other emirates solely rely on MOHAP to oversee their regulatory functions. In addition to their separate healthcare authorities, the emirates of Dubai and Sharjah have also established healthcare free zones namely Dubai Healthcare City ("**DHCC**") and Sharjah Healthcare City to attract foreign direct investment in the healthcare sector. The following section provides an overview of the aforementioned regulators and other authorities regulating the healthcare sector in the UAE.

MOHAP

MOHAP being a federal authority focuses on the implementation of a common healthcare policy uniformly across all the emirates. MOHAP's supervision in the healthcare sector ranges from licensing of healthcare providers and products to formulation of general programs for prevention of diseases etc.

DOH

DOH is the regulatory body of the healthcare sector in the Emirate of Abu Dhabi which is entrusted with responsibility of monitoring and analyzing the performance of the sector in the emirate. DOH is further responsible for promulgating a strategy to ensure the effective implementation of the practices related to healthcare as per international quality standards.

DHA

Since its establishment, pursuant to the Dubai Law No. 13 of 2007, the DHA has been regulating the healthcare services, healthcare providers and the healthcare insurance in the Emirate of

Dubai. It is entrusted with managing all public healthcare facilities in Dubai and also with the licensing of private sector facilities. The DHA is further supported by two of its subsidiaries in carrying out its regulatory functions in the emirate namely Healthcare Corporation and Dubai Health Insurance Corporation..

SHARJAH HEALTH AUTHORITY

The healthcare sector in the Emirate of Sharjah is overlooked by the Sharjah Health Authority established pursuant to the Sharjah Emiri Decree No. 12 of 2010 (amended by Emiri Decree No. 33 of 2016).

DUBAI HEALTHCARE CITY AUTHORITY

Dubai Healthcare City Authority (DHCCA) is a government owned corporation responsible for regulating the Dubai Healthcare City free zone. The authority ensures that its healthcare policies are focused on making Dubai the international healthcare and medical hub by attracting foreign direct investment from renowned medical and healthcare companies around the world. In order to achieve these goals, DHCCA is entrusted with powers ranging from development of policies and procedures and consequently with the powers to enforce the same in order to achieve the desired aims.

Health Authority Abu Dhabi (HAAD) / Abu Dhabi Health Services Company (SEHA)

HAAD, after having been established pursuant to Abu Dhabi Law No. 1/2007, oversees the healthcare-related services in the capital of the UAE whereas some of its managing functions are devolved to SEHA.

III. Regulatory Requirements for Companies under the Healthcare Law

Healthcare companies must follow various regulations regarding the sale and marketing of medical products in the UAE. These regulations are primarily contained in the Healthcare Law and its Implementing Regulations. MOHAP and the other regulatory authorities in the respective emirates are collectively responsible for ensuring the adequacy of any medical product sold in the country. Apart from other regulatory requirements, the two most important ones for companies to do business in the healthcare sector of the UAE are obtaining the marketing authorization and product registration from the authorities. These two requirements are briefly discussed hereinbelow.

Marketing Authorization

Under the Healthcare Law, no medical product in the UAE may be traded unless a marketing authorization ("**Marketing Authorization**") has been granted by MOHAP. For all medical products, a specific Marketing Authorization is required before they are made commercially available in the country and once such an authorization has been obtained then it is incumbent upon the holder of the Marketing Authorization ("**Marketing Authorization Holder**") that it must only promote the authorized medical product for the purposes the approval was granted.

MOHAP only issues a Marketing Authorization certificate after ascertaining the product's

efficacy, safety and compliance and other marketing authorizations issued to the product by the reference countries and lastly on the premise that the applicant has the intellectual property rights to market the applied product. Furthermore, companies are required to appoint one or more qualified persons residing in the UAE and licensed by the relevant UAE authorities. The appointed person(s) will be equally responsible along with the Marketing Authorization Holder for the compliance with all regulatory requirements laid down under the Healthcare Law.

In addition to the aforementioned, the Marketing Authorization Holder is also required to appoint one pharmaceutical establishment to exclusively import its products into the UAE. The distribution in the UAE market can be undertaken by several UAE companies as per the new Healthcare Law. Lastly, additional requirements in the form of an adequate warehousing facility, distribution channels for the distribution of the products and periodical notification to MOHAP regarding the performance of the product also apply to the Marketing Authorization Holder / an applicant seeking market authorization.

Furthermore, the DHA or the HAAD may need to review the contents of the advertising/ marketing of medical products/pharmaceuticals prior to them being implemented in that Emirate on a case-by-case basis. Only when companies can fulfill all these requirements a Marketing Authorization is issued by MOHAP.

Obtaining Marketing Authorizations

Traditionally, the process for obtaining the marketing Authorization was conducted through one exclusive agent in the UAE who was entrusted by the foreign principal to register with the Ministry of Economy and apply for the authorization to market, advertise, import and distribute the medical products. However, under the Healthcare Law, the Marketing Authorization Holder may be a foreign-owned company licensed in the UAE which employs one or more qualified persons. For the import of the products, an exclusive importer owned by an Emirati national will still be required but more than one company may be appointed as a distributor, i.e. the distributor does not have to be appointed on an exclusive basis any longer.

Product Registration

In line with the requirement of Marketing Authorization MOHAP has issued stringent guidelines for the registration of medical products in the country. The strict regulatory framework for the registration of medical products is a testament to the UAE government's commitment to ensuring that no unsafe or ineffective medical products enter the local market and ensuring that quality medical products are available for the residents. In the interest of brevity, hereinbelow, we will briefly look at the requirements and process of the registration of medical devices in the UAE.

MOHAP has developed a comprehensive criterion for medical device registration in the country which is based on internationally recognized and accepted rules and regulations such as the EU Medical Device Directive (93/42/EEC) and the guidelines issued by the US Food and Drug Administration.

Pre-Requisites for Registration of Medical Devices

The application for registration of medical devices can only be made by the device

manufacturer or its local representative in the UAE. In case the application is being filed by the local representative then such a representative is required to be formally authorized by the manufacturer to represent it during the pendency of the application process and thereafter. As a pre-condition, the Marketing Authorization Holder must have a medical warehouse licensed by and registered with MOHAP. Once these pre-conditions are fulfilled only then an application for device registration can be filed.

Documents Needed for Registration

The registration of medical devices is subdivided into different classes. The classification is based on the time period for which the device is being registered and its potential impact on the patients on whom the device is intended to be administered post its registration. Therefore, the class in which the registration is sought determines the amount of information that the Ministry of Health will evaluate before giving its approval. The application is required to be supported with evidence of the efficacy of the device, its manufacturing and previous use (if any). Depending on the classification of the device, among others, the following documents may be required to be submitted along with the application:

- Signed and stamped application form;
- A copy of the valid registration certificate of the manufacturing facility;
- A valid certificate of free sale/ registration issued by the competent authorities in the country of origin certified by the Embassy of the United Arab Emirates;
- A copy of the product agency contract signed between the company and the agent;
- Certificate of quality conformity/ marketing authorization;
- Copies of the product registration certificates in other countries;
- Product information, including the following: description, formulation, types, sizes, models, accessories, usages, side effects, contradictions, warnings, precautions, usage guidelines, photos of packaging covers, brochures and user manuals; and
- Documents certifying the efficacy and safety of the product.

In addition to the above, the applicant is required to certify to MOHAP that all the information is true, and applicant will be fully responsible for the performance of the device and its post-market plan.

Procedure of Registration

Lately, the process of registration has been made available online. Applications are submitted online along with all the relevant documents through a registered portal on the e-services tab of MOHAP's website. Once the application is submitted, it is deliberated upon by the technical committee before forwarding it to MOHAP's Committee on Drug Registration which takes the final decision on whether or not to register the applied product. The product, if approved, is registered for 5 years. Companies are also required to follow certain post-registration requirements which include monitoring of the product for any potential issues related to quality and safety and in case a company fails to comply with these requirements MOHAP's Drug Control Department is empowered to revoke the registration.

IV. Incorporating a Company in the UAE's Healthcare Sector

Due to its growth potential, the UAE's healthcare sector is one of the most attractive sectors for foreign companies to invest in. This section will briefly analyze the options available to foreign investors to set up their operations in the country.

One model for any foreign investor is to establish a subsidiary company in the UAE to import healthcare-related products into the country. Even though the import of drugs and certain other medical products may only be done by a registered commercial agent, other products which are not subject to these limitations may be imported by a company resident in the UAE but owned fully or partially by foreign investors.

Until recently, UAE law imposed certain restrictions on foreign investors wishing to establish their own healthcare business in the UAE mainland. To set up a local subsidiary/company in the mainland, they were required to take on board one or more UAE national partners who were required to hold at least 51% of the company's shares.

As part of the comprehensive legislative reform undertaken in the year 2022, a new Federal Commercial Companies Law (Federal Decree-Law No. 32 of 2021 On Commercial Companies) was enacted, which came into force on 2 February 2022 and replaced the previous Commercial Companies Law of 2015 (Federal Law No. 2 of 20115). Under the new law, foreign investors are allowed to own 100% of the shares in a UAE mainland company. Only with regard to certain activities/products restrictions might apply.

V. Collaborating with a Commercial Agent / Distributor

As mentioned above due to the ownership and control restrictions and stringent regulatory framework, the appointment of a commercial agent has often been the only choice for foreign investors for importing medical products into the UAE. Under this model, a foreign investment company collaborates with the local agent to import and market its products in the territory. The agent in return for an agreed remuneration represents the foreign investor in all the regulatory and commercial matters in the country. Under the Federal Law No. 18 of 1981 on the Regulation of the Commercial Agencies ("**Commercial Agency Law**"), the agent is defined as a natural or legal Emirati person who is authorized under the commercial agency contract to represent the principal. In case the agent is a local company, this must be owned 100% by UAE nationals. Since 2020, Public Joint Stock Companies, of which at least 51% of the shares are held by UAE nationals are also allowed to act as agents. The Commercial Agency Law not only applies to "classic agents", i.e., a person or company acting on behalf and for the account of the foreign principal, but also to local distributors who sell the products on their own behalf and for their own account.

The concept of commercial agency offers foreign investors an easy way to penetrate the local market without having a physical presence. Furthermore, businesses stay away from the arduous regulatory processes. However, despite its certain commercial benefits this mode of business has at times proven to be problematic, therefore, foreign companies looking to conduct business through a commercial agent must consider certain factors which will be discussed hereinbelow.

Exclusivity of commercial agents/distributors

Article 5 of the Commercial Agency Law protects the agent/distributor through the exclusivity principle, i.e., the principle is barred from appointing another agent/distributor for the same territory. This protection afforded to the local agents/distributors has proven problematic for foreign principals in cases where the collaboration has not been commercially viable any longer due to the performance of the agent/distributor. As long as the agency has not been deregistered, no new agent/distributor can be appointed. The deregistration from the register can only be applied for by the agent/distributor or ordered by a competent court. In addition, an exclusive and registered agent/distributor has the right to block all imports of the goods subject to his agency from being imported into the UAE. Hence, in case of a dispute between the agent and the principal, agents have the option to use this right to the detriment of the principal and place pressure on the principal.

However, with the enactment of the Healthcare Law the foreign companies can now appoint more than one distributor and it is yet to be seen how this change will influence the legal landscape of medical product distribution in the UAE.

Termination of agency

The termination of a registered agency in the UAE can be an arduous task for foreign businesses linked to certain liabilities due to the statutory protections afforded to local agents. The Commercial Agency Law protects agents from being terminated without a material reason whereas the law does not clarify what constitutes a material reason. In practice, UAE courts have upheld certain reasons for termination such as failure to achieve sale targets, breach of contract which caused material losses, transfer of an agency to a third party etc. However, these instances are rare and legal acknowledgement can involve a lot of time and costs. If the existence of a material reason is denied, high compensation claims against the principal are likely to be granted to the agent by the courts. Before a party can refer its claim to the courts it has to approach the agency dispute committee which will issue a decision on the matter. If neither party approaches the courts within a certain time after the issuance of the dispute committee's decision, such a decision will become final and binding.

Mitigating risks

Owing to the exclusivity of the commercial agents and given the hurdles in terminating such a relationship, foreign businesses are advised to select their local partners prudently and with utmost care. If the activity or range of products does not require a registered agent/distributor, businesses should consider either appointing a local partner on a non-exclusive basis or using other means to avoid its registration with the Ministry of Economy.

Once a partner is chosen then it is incumbent upon the businesses to have a well-drafted agency agreement with a specific and comprehensive catalogue of the agent's duties including binding sales targets. Only if the agent's duties are crystal clear can a violation of duties qualify as "material violation" and thus allow the principal to terminate the agency. In addition, the contract should clearly define the limitations with regard to actions, areas, and products. As an additional protection for the principal and to test a newly appointed agent's capabilities and professionality, such agent could, at first, be granted a limited contract area only (e.g., only

one Emirate instead of the entire UAE) and the range of products could be strictly limited to certain product lines. Depending on the details of the case, other protective measures could be considered by the principal.

Saudi Arabia

A. Introduction

The Kingdom of Saudi Arabia ("**Saudi Arabia**" or "**Kingdom**") is the largest economy in the Middle East ruled as an Islamic absolute monarchy by its current King Salman bin Abdulaziz Al Saud. The country is undergoing vast reforms which are being driven and overseen by the King's son and designated successor, Crown Prince Mohammed bin Salman.

The Saudi economy is largely dependent on oil exports. Accordingly, the economic landscape of the country has strongly evolved in and around this sector with Saudi ARAMCO, the largest oil firm in the world, being a substantial factor. Crown Prince Mohammed bin Salman outlined his core policies in the so-called Saudi Vision 2030, a holistic project which is set to shape the Kingdom's society and economy.

One of the central goals of the Saudi Vision 2030 is to reduce the country's dependence on oil and to diversify its economy. In line with these goals, Saudi Arabia has recently introduced numerous reforms aimed at increasing its attractiveness to foreign investors.

B. Market Analysis: Saudi-Arabia

The Saudi-Arabian healthcare sector is currently undergoing a transformation. The healthcare sector is expected to grow 10% over the next years. Saudi Arabia is the largest spender of healthcare in Middle East and North Africa. In 2019 the health expenditure per capita was around USD 1,316 or 5.7% of GDP (WHO Global Health Expenditure Database).

According to the Ministry of Health (MOH) the sector must overcome numerous challenges. Health care cost is constantly rising, driven by an ageing population, change in disease pattern and medical innovations. At the same time, budgetary resources are under pressure. The Ministry of Health has launched one of the world's largest healthcare sector transformation programs to optimize clinical outcomes, cost and responsiveness of the overall system.

Under the Saudi Vision 2030 the new healthcare strategy is based on 7 themes advancing the transformation:

- Patient Centric Model for Care (prevention, evidence-based pathways)
- Insurance based financing
- Private Sector Participation
- Independent Governance
- Human Capital
- Digital Healthcare
- Corporatization of public hospitals and the transition into 20 Accountable Care Organizations

Private Sector participation has already started. Until 2030, 295 out of the 329 government hospitals are planned to be privatized. Therefore, the government is aiming for investments from abroad (GTAI).

Since 2017, healthcare facilities can also be 100% foreign owned. In the period from 2015 to 2020, hospital capacities increased by 10,600 to 78,596 beds, of which 75% were state-owned facilities. There were 337 state hospitals and 167 private hospitals. Currently, projects worth around USD 10 billion are under construction in the health sector, with projects worth over USD 3 billion in the pipeline.

To implement the goals of the transformation process, the Kingdom has also released a five-year E-Health National Strategy. The plan is an important tool to achieve the goals set in the transformation process and to achieve a comprehensive patient healthcare management system. Aim is to improve the care of patients, connect providers at all levels of care, measure the performance of healthcare delivery and transform healthcare delivery to a consistent world-class standard. Electronic health records, electronic medical records and critical decision support systems are some of the applications looked into.

Another component of e-health is telemedicine. In June 2019, the Telemedicine Regulation has been published. Telemedicine centers are classified as Support Health Services.

In order to reduce the overall spending, several initiatives for preventive care like the “Quality of Life Program”, focusing on fitness and preventive care have been launched. To control and prevent the occurrence of lifestyle-related diseases such as diabetes a National Executive Plan has been developed by MOH. Home healthcare services are also a new trend in the Kingdom reducing the cost.

The trend in the GCC is shifting from a fee for services to a value-based healthcare model that focuses on enhancing treatment outcomes while lowering costs. Saudi Arabia is spearheading this development in the region with the objective to establish 20 regional Accountable Care Organizations across the Kingdom and the implementation of a comprehensive Population Health Management. The transformation will see the establishment of a regulator (MoH), a single public payer and a health holding company with the objective to oversee the transition of public providers into the Accountable Care Organizations.

Institutional Framework

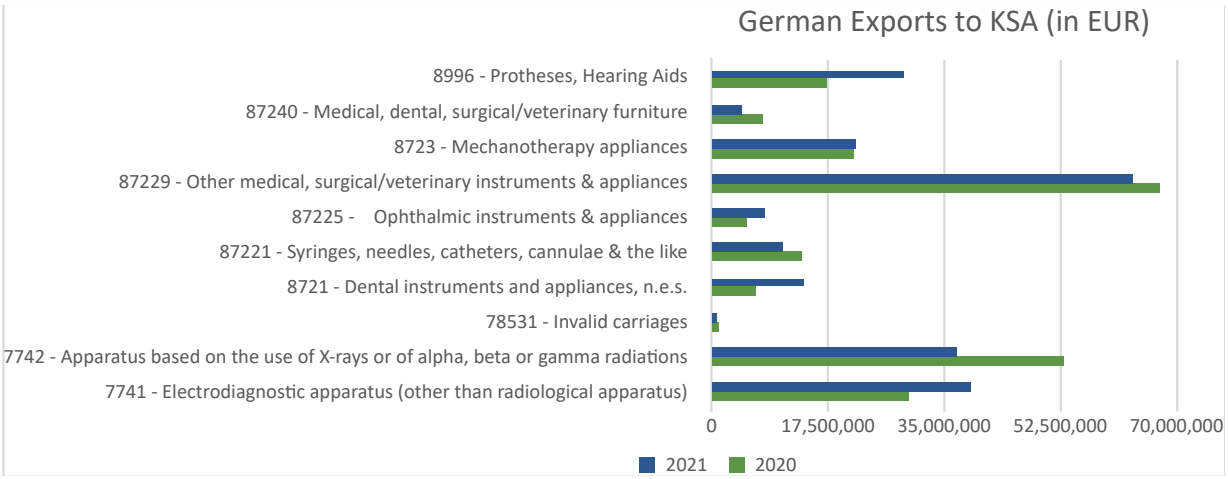
The following institutions are relevant actors in the Health care sector of Saudi Arabia:

- Ministry of Health: provides healthcare/promotes public health prevention and develops laws and legislations
- Saudi Health Council: Liaisons between multiple health sectors
- Saudi Food and Drug Authority (SFDA): Develops and enforces health standards and regulates the sector (safety, quality, efficacy of drugs, food and medical devices)
- Saudi Commission for Health: Assures effectiveness of health practice registrations and promotes medical research and education.
- The Council of Cooperate Health Insurance: Supervises and controls insurance companies and service providers..

Medical Equipment Market

90% of the medical equipment is imported into the Saudi market (GTAI). The local production is limited to the production of injections, bandaging material etc. The USA and Germany are the main exporters into the market.

German exports of medical equipment were at EUR 228 million in 2021, a 2% increase compared to 2020 and a 10% increase compared to 2019.



Source: Eurostat, 2022

Procurement for medical equipment is done through tenders. The largest number of tenders is published by government entities. The National Unified Procurement Company (NUPCO) (https://www.nupco.com) is bundling the procurement of government healthcare entities. It is the source of supply for government entities also offering logistic services. It caters to government hospitals, military hospitals, laboratories, pharmacies, manufacturers, and retailers.

Medical Equipment must be registered before being imported into the Kingdom. The Saudi Food and Drug Authority, SFDA (https://www.sfda.gov.sa/en) has launched a Medical Device Establishment Licensing System (MDEL) for establishments presently involved in the importation

and/or distribution of medical devices on the Saudi market. The applicant must be registered in the Medical Devices National Registry (MDNR) and shall ensure to appropriately manage the imported and/or distributed devices in relation to storage, transport, traceability and installation.

C. Legal Framework in the KSA Healthcare Sector

I. Healthcare Legislation

Saudi Arabia has a unique and distinct legal system based on Islamic law (sharia), which is based on religious sources. To complement this, particularly in the area of trade and commerce, as well as administrative law, the Kingdom issues specific laws on distinct matters. The healthcare sector is largely subject to such legislative activity and thus presents a very similar legal landscape to other countries. The Kingdom of Saudi Arabia has triggered an unprecedented social and economic reform program spearheaded by its Vision 2030 where the healthcare sector plays a pivotal role. As all public administration, the current healthcare legislation may be subject to far-reaching reforms and amendments anytime in the future to an overwhelming extent. This means that international standards and practices are more and more incorporated into the Saudi legislative and regulatory systems to which the healthcare sector should be no exception.

The general legislation outlining the Kingdom's approach to health matters is the General Health Law ("GHL") enacted by Royal Decree M/11 dated 23/03/1423 H equivalent to 4 June 2002. The GHL outlines the healthcare commitments of the Kingdom on primary, secondary, and tertiary stages of healthcare.

The GHL is the centerpiece of Saudi-Arabia's health legislation. It is however flanked by other laws regulating specific fields of the healthcare sector.

II. Regulatory Authorities

In comparison to other states of the region (especially the UAE), Saudi Arabia is a unitary state with a centralized administration. This provides one regulatory framework throughout the country, a unified market and clear competence of authorities with little to no local differences.

The Ministry of Health of Saudi Arabia ("**MoH**") was established by a Royal decree in 1951. As per the GHL, it assumes any health-related matters, unless the task has been assigned to another unit. The main responsibility for medical products has been detached from the MoH and assigned to the Saudi Food & Drug Administration ("**SFDA**") by virtue of Royal Decree RD M/6 dated 25/01/1428 H equivalent to 13 February 2007. The SFDA is an independent body with legal personality and is directly linked to the Prime Minister. It assumes all procedural, executive and monitoring tasks to ensure the safety of food and medicine for humans and animals and the safety of biological and chemical preparations as well as electronic products that affect human health.

III. General Regulation of Medical Products

Until recently, medical products have been regulated by the SFDA in its Supervisory Regulation on Medical Devices and Products enacted by Decision of the SFDA Board of Directors No. (1429-

8-1) on 29/12/1429 H and amended by Decision of the SFDA Board of Directors No. (1439-16-4) on 9/4/1439 H ("**Regulation**") – sometimes also commonly referred to as the "Interim Regulation".

This regulatory base has now shifted. By virtue of Royal Decree M/54 dated 06/07/1442 H (corresponding to 18 February 2021), Saudi Arabia enacted a new law on Medical Devices and Products which entered into force 180 days after its publication in August 2021 (the "**Law**"). Core stipulations of this Law touch on the procedures and conditions of admission of medical products to the market. The Regulation largely quoted to adhere to standards of the Global Harmonization Task Force ("**GTHF**"). Since the GHTF was disbanded late in 2012, the KSA regulators and legislators had to define new (international) standards and procedures for products to adhere to.

Executive Regulations to the Law ("**ER**") have been enacted by virtue of SFDA Board Decision No. (1443-29-3) dated 19/2/1443 H and were published in the Official Gazette on 21/04/1443 H (26 November 2021). They took effect from the same date as the Law.

In accordance with the Law, a medical device is any apparatus, instrument, implement, implant, laboratory reagent or calibrator, operating program or material for medical devices or other similar or related instrument manufactured alone or with other devices, used in the diagnosis, prevention, monitoring, control, treatment or alleviation of diseases or injuries or in the compensation for injuries, and likewise used in the examination, replacement, modification or support of the anatomy or the physiological impact, in supporting or sustaining life (vital functions), in the control of conception, in the disinfection of medical devices and supplies and in providing information - for medical or diagnostic purposes - based on the laboratory tests performed on samples taken from the human body, and which cannot achieve its intended purpose in or on the human body by medications, immunological factors or metabolic transformations but assists them in achieving their intended effects.

For most services of the SFDA, the authority provides web-based registries and portals.

A manufacturer from outside the KSA shall appoint an authorized representative to act on his behalf. This representative must fulfil several qualifications to be acceptable to the SFDA such as:

- Residing in the Kingdom.
- Holding an SFDA facility license as an authorized representative for each manufacturer he represents in the KSA
- Committing to applying the quality management system as per the ER,
- Being certified to carry out the operations necessary to perform the tasks assigned to him, and able to prove this with the relevant documentation, and
- Committing to fulfilling any other requirements requested by the SFDA and published on its website.

Basis for the relation between the manufacturer and the authorized representative is a contract concluded between both parties and comprising at least the following information:

- Determination of the activities which the authorized representative undertakes on behalf of the manufacturer in the latter's dealings with the SFDA,

- The class or group of devices to be marketed in the KSA,
- The authorized representative's commitment to all post-marketing control requirements published on the SFDA website, and
- Determination of the term of the agreement between the two parties and termination procedures in accordance with the Law and the ER.

In the agreement with the authorized representative, the manufacturer commits to the following obligations and responsibilities

- Exclusivity of the authorized representative for the same type or general group of devices and equipment, (a different authorized representative may be appointed for each type or general group of medical devices and equipment),
- Written termination requirement for the manufacturer,
- Undertaking of the manufacturer to appoint a new authorized representative and transfer all previous obligations to him immediately upon the termination or non-renewal of the agreement of the former authorized representative, and the manufacturer's obligation to notify the SFDA accordingly, and
- Providing any other information or documents requested by the SFDA.

In return, the authorized representative commits to the following obligations and responsibilities

- Representing the manufacturer in its dealings with the SFDA,
- Cooperating with the SFDA in studies and procedures taken during post-marketing control,
- Informing the SFDA of any accidents that occurred outside the KSA and that have consequences on devices or equipment circulating in the KSA, with explanation of the circumstances and provision of information on the corrective measures taken or intended to be taken by the manufacturer,
- Informing the SFDA of all corrective actions resulting from the post-marketing follow-up investigations conducted by the manufacturer for the devices and equipment traded in the KSA, with an explanation of the reasons for the corrective actions and providing information on the actions taken or intended to be taken by the manufacturer,
- Cooperating with persons who engage in activities that are subject to the provisions of the Law and the ER with respect to devices and equipment that are traded in the KSA in accordance with the agreement concluded between the authorized representative and the manufacturer,
- The responsibility of the authorized representative for the devices and equipment covered by the agreement does not vanish upon the request to terminate the agreement, unless the manufacturer appoints a successor, or when the devices and equipment are not available in the market and with users,
- Written termination requirement for the authorized representative,
- Providing any other information or documents requested by the SFDA.

In such relationships, the SFDA carries out the following:

- Verify that the information provided by the applicant is sufficient and meets the requirements of the ER,
- Verify that the executive procedures of the authorized representative are appropriate for the performance of the tasks entrusted to him,
- Issue a license for the facility for a period of one year or similar periods - a maximum of five years - when the requirements in the ER are met, subject to renewal,
- Evaluating any changes to the agreement signed between the authorized representative and the manufacturer and take appropriate measures if necessary.

IV. Regulatory requirements for Entities

Registration

An entity assuming any of the activities regulated by the Law is subject to registration with the SFDA. These activities include:

- Designing and manufacturing medical devices and equipment,
- Importing, marketing, distributing and storing them,
- Services to verify compliance of medical devices and equipment with the applicable technical regulations and the quality management system, as well as quality assurance verification,
- Verification of clinical studies,
- Technical consulting services in the field of medical devices and equipment,
- Examination of devices and equipment to ensure their compliance with the applicable technical regulations and standard specifications,
- Maintenance services,
- Representation of manufacturers domiciled outside the KSA.

Unless exempted by SFDA, it is only allowed to circulate any medical device or equipment after registering it and upon obtaining a marketing permission.

Hence any person exercising any of the aforementioned activities as well as manufacturing devices themselves are subject to registration.

Licensing

Beyond pure registration, some entities require an additional establishment license from the SFDA. General licensing requirements for any entity are:

- Creating/opening an account in the electronic system of the SFDA and obtaining a facility number for the entity,

- Submitting an application with the SFDA and all relevant information/documentation through the electronic system to obtain a license to practice the desired activity,
- Paying the relevant fees, and
- Any other procedures requested by the SFDA and published on its website.

There may be further specific licensing requirements for importers, distributors, warehousing etc. Especially manufacturing medical devices may be subject to relevant regulations and licenses for manufacturing in addition to specific SDFA licensing.

There may be visits to the facility by SDFA representatives to ensure the establishment, documentation and application of the quality management system in accordance with the ER.

The SFDA must be informed in case of modification of the license through the electronic system and the required documents shall be submitted accordingly.

V. Regulatory Requirements related to Products and Transactions

All medical devices/products introduced into the KSA, offered on its markets or used in the country must be listed with the SFDA and must have a written marketing allowance from the SFDA unless the SFDA itself has dropped this requirement for certain medical devices/products mostly classified as low risk by the SFDA.

Marketing Authorization

For each medical device to be placed on the KSA market, the manufacturer must obtain a marketing authorization from the SFDA. To obtain this authorization, the applicant must provide at least:

- The manufacturer's contact information,
- Contact, identity and registration information of the authorized representative,
- The name of the person responsible for completing the request for the marketing authorization and his contact information.
- An undertaking from the manufacturer to inform the Authority of all the procedures and measures taken, potentially affecting the device, in accordance with the requirements for post-marketing control of medical devices and equipment.

For the technical documentation of the device, the application must contain at least

- The necessary documents evidencing compatibility of the device with the basic principles of safety and performance specified in the requirements for the permission to market in the Kingdom,
- The technical documents specified by the SFDA, usually including:
  - » A description of the device and its characteristics, including components and accessories,
  - » Designing and manufacturing information,

  - Risk management evaluation file,
  - Verification and validation of the product, including clinical studies,
  - A post-marketing control plan, and
  - Periodic safety update reports and post-marketing control reports.
- A copy of the labelling information and ensuring that the elements and contents of the labelling card fulfil the purpose for which the device was manufactured,
- Information on the measures related to the environment and/or usage conditions in KSA,
- Classification of the device as per the classification rules mentioned in the ER,
- Evidence of the manufacturer applying the quality management system as per the ER,
- Proof of compliance with the Technical Regulations or relevant standard specifications determined and published by the SFDA,
- An undertaking that the device conforms to the provisions of the ER, and
- Any other requirements requested by the SFDA and published on its website.

In case deemed necessary, the SFDA may request additional technical documents before deciding on the application for marketing authorization. A marketing authorization may include several devices. The authorization certificate is issued for a maximum period of three years from the date of its issuance. Renewal must take place before expiry and through the electronic system.

A refusal to issue a marketing authorization must contain reasons. Furthermore, the SFDA may withdraw or suspend the marketing authorization if it detects or suspects a non-compliance with the relevant requirements. The SFDA must inform the manufacturer or its authorized representative of the reasons for such action and of the means for appeal.

Any information and documentation submitted to the SFDA through the electronic system must be updated within 10 or 30 days depending on the importance of such information.

Advertising

Advertising of medical devices is subject to a prior marketing authorization.

Advertising material must not mislead the user regarding the performance of the medical device as specified by the manufacturer. Advertising to the general public (including over the internet) has to avoid misleading laypersons. Any advertising to persons qualified to use medical devices shall include the relevant information compatible with their specific needs. All advertisement material must be approved by SFDA.

Medical sales representatives must have sufficient knowledge to be able to provide appropriate information about the medical devices they promote.

VI. Establishing a Direct Presence in the KSA's Healthcare Sector

The KSA is by far the largest market in the GCC with a projection of a continuously growing demand. It has proved to be interesting not only for the trade of medical products but also for local production (so far especially for generic drugs). This might be one of the driving motivations for foreign direct investment in the KSA, by either establishing an own corporate vehicle (branch or company) or a local joint venture company.

Foreign Investment License

All foreign investment in the Kingdom (unless from another GCC jurisdiction) is subject to an investment license, regardless of a JV with a KSA partner or a whole foreign investment. Licenses are issued and administered by the recently established Ministry of Investment in Saudi Arabia (MISA).

In most sectors, KSA allows for 100% foreign investment regardless of the legal shape of the envisaged vehicle.

Licenses are given for different categories (e.g., industrial, commercial, service) and must state the envisaged activities. Certain licenses and activities can be subject to nationalization or capital requirements. Most notable is the license for commercial trading, which has a minimum share capital requirement of SAR 30 million in cash in case of a 100% foreign-owned entity and SAR 200 million to SAR 300 million of investment in the first 5 years of licensing. An entity of up to 75% foreign shareholding needs a minimum capital of SAR 26,666,667 of which the foreign shareholder may not contribute less than SAR 20 million. If the investor chooses to aim for a one-person joint stock company, the minimum capital would be SAR 5 million. A general minimum of foreign capital to invest in order to obtain a MISA license other than for commercial trading would usually be set at SAR 500,000 or even less.

Prohibited activities for foreign investment relevant to the medical sector would be commission agents, services provided by midwives, nurses, physical therapy services and quasi-doctoral services as well as poison centers, blood banks and quarantine. Further restrictions on nationality might be found within individual sectorial regulations.

Corporate Vehicle, Incorporation & Registration

Foreign investors can usually choose any of the available corporate vehicles under KSA Law for their venture. The most popular vehicles would be a branch of a foreign company as well as a company with limited liability (LLC). The LLC would only be liable for its own debts and the liability of the shareholder is limited to the share capital to be paid up by him. This is usually seen as an advantage. However, the LLC would have to be incorporated as a legal person with an individual Memorandum of Association with the associated procedures of approval from the Ministry of Commerce (MC) as well as notarization of its company documents. The registration of a branch faces fewer procedural obstacles but maintains full liability for the parent.

All commercial entities would have to be registered in the commercial register.

Further licenses

KSA-based corporate vehicles involved in the medical devices business sector would also be subject to Registration and Licensing with the SFDA as a regulatory body.

VII. Collaborating with a Commercial Agent / Distributor

As in most jurisdictions within the GCC, KSA legislation most notably Royal Decree No. 11 dated 20/02/1382 H. (corresponding to 22 July 1962) containing the Commercial Agency Law stipulates special protection for local commercial agents and distributors. Thus, collaborating with a commercial agent/distributor in the KSA should be considered carefully and the advantages of an easy market penetration should be counterweighted to potential risks.

From a practical point of view, many foreign manufacturers combine the functions of their authorized representative and a commercial agent/distributor.

Distributors and importers are largely subject to the same licensing requirements. These include:

- Submitting the data of the manufacturer, the medical devices and supplies to be imported, in addition to the data of the authorized representative of the factory residing outside KSA,
- Submitting a documented procedure to track the medical device or equipment during the import or distribution phase, submit an undertaking to implement the procedure and adhere to it,
- Submitting a documented procedure for storing and transporting the medical device or equipment according to the requirements of the manufacturer, and submit an undertaking to implement the procedure and adhere to it,
- Providing evidence of the implementation of the legally required quality management system,
- Appointing an authorized person for the facility to deal with the SFDA.

Further, licensed distributors and importers are subject to the following ongoing obligations:

- Acting in accordance with the licensing requirements mentioned in the preceding paragraph,
- Complying with the requirements of the manufacturer in addition to the requirements published by the SFDA on transportation and storage of medical devices and supplies,
- Ensuring present and complete documentation for each medical device or equipment including e.g.:
    - » The marketing authorization certificate,
    - » A declaration of conformity that indicates the compliance of the device or equipment with the requirements of the Law and the Regulation, signed by the manufacturer,
    - » The labelling code of the device or equipment, including its machine-readable code in conformity with its technical requirements,

  - Labelling information,
  - Details of contact with the manufacturer, and its authorized representative if the manufacturer is outside KSA,
- Importing and/or distributing only such medical devices and equipment that comply with the requirements of the Law and the Regulation,
- Providing sufficient and appropriate number of human and other resources to meet the requirements specified in the Law and the Regulation.

Nationality and Exclusivity

Saudi Arabia requires officially registered commercial agents or distributors to be 100% KSA-owned. This means that even legal persons (i.e., companies) must ultimately be owned completely by individuals with Saudi nationality.

KSA agency legislation does not contain provisions granting exclusivity to the agent and/or distributor. If such conditions are agreed by the parties to such agreement, they would just apply between them. An agent/distributor would thus be able to sue the principal for breach of contract, but it could not stop products from entering the country.

Terminating an agency

The Agency Law does not elaborate how to terminate an agency in form and reason. It is therefore highly recommended to list the reasons for a unilateral termination in the contract as well as the calculation of potential damages in case of such termination. Practical experience shows that KSA courts allow for the unilateral termination of an agency but would meticulously screen for adherence to reasons and procedures stipulated in the contract. Many terminated agents/distributors would try and sue for damages after a termination event. Their claims not only contain damages for stock of expenses made in reliance on the existing agency relation but also for loss of reputation etc. Courts might be inclined to grant damages when procedures and contractual stipulations were not carefully observed.

Qatar

A. Introduction

The Emirate of Qatar is a monarchy, ruled by the house of Thani since 1868, to a great extent with consolidated legislative, executive and judicial bodies. The country with the third largest reserves in natural gas and oil and fourth-highest GDP in the world counts a population of only about 3 million people of which 88% are expat workers from around the world. Qatar is ambitiously working on the implementation of the National Vision 2030, which provides a framework to implement national strategies focusing on transforming Qatar into a more advanced country.

The human health and social work industry adds over USD 4 billion to the Qatari gross domestic product. Qatar's five health centers (Al Wakrah, Al Mashaf, Al Saad, Al Khor and Ain Khaled) received expansions to keep up with the ever-growing demand and to establish the country as a regional and global leader in the sector, designed for medical tourism. With rarely local producers of pharmaceuticals, the country is however highly dependent on imports.

B. Market Analysis: Qatar

Qatar's health sector has undergone an enormous expansion in recent years and provides today for a full range of high-quality healthcare services to more than 2.8 million people living in the country. The country's healthcare spending is among the highest in the Middle East. In 2019, the State invested QR 22.7 billion (USD 6.2 billion) in the sector (11% of its total budget).

Having benefited from huge state investments, Qatar's public hospitals and clinics are well-equipped and employ highly proficient medical staff. With approximately 77.4 physicians per 10,000 people, Qatar has one of the highest health workforce densities in the world. The public healthcare system operates through the state-run Hamad Medical Corporation (HMC). Qatari

nationals, or those with Qatari residency status, are provided with heavily subsidized and extensive public healthcare at HMC clinics or hospitals. Public services are accessed through a government-issued health card, which can be applied for at any HMC healthcare center.

Private healthcare in Qatar is a fast-growing sector and is driven by both popular demand for quicker service as well as the gradual increase in Qatar's population. Private healthcare provides more options for specialized procedures. In order to meet the increasing demand for healthcare services and share the financial burden on state finances, Qatar is set to attract FDIs through PPP initiatives in the healthcare sector.

Medical Equipment/Devices

The Qatari government is constantly upgrading the quality of health services, drawing heavily on imported technology and equipment, as well as international expertise and knowledge. According to industry estimates, the market for medical equipment will grow over the next five years and the market relies heavily on imports from Europe, Asia and the United States. In 2019, Germany exported medical equipment worth approx. EUR 30 million to Qatar.

The government offers a range of incentives to encourage more local companies to venture into this expanding market and set up manufacturing facilities in the country. Because of the Covid-19 pandemic, in mid-2020, Qatar began manufacturing artificial respiratory machines to meet domestic healthcare needs; production in excess of local demand will be exported. Moreover, the supply chain constraints from international companies have also prompted government and authorities to encourage and procure supplies from the domestic market.

C. Legal Framework in the Qatar Healthcare Sector

I. Healthcare Legislation

Although there is no single codified legislation dealing specifically with registration, import and regulation of medical devices, the healthcare sector in Qatar however is regulated through multifarious legislative instruments which directly or indirectly ensure the safety and standards of medical devices and products being imported into the country. Among others, the major legislative instruments are the following:

- Qatar Law No. 2/1983 On the Practice of the Profession of Medicine, Dentistry and Dental Surgery;
- Qatar Law No. 1/1986 on the Registration of Pharmaceutical Companies and their Products;
- Qatar Law No. 7/1996 on Regulating Medical Treatment and Health Services within the State; and
- Qatar Emiri Decision No. 13/2009 on Establishing the Supreme Council of Health.

Regarding the mechanism of registration of implantable medical devices for import and use, the Qatar Ministry of Public Health issued Memo No. 3/2021 in April 2021, a Regulatory outlining the details of the registration process for implantable medical devices.

In addition, the following are the important policy instruments regulating or anchoring the healthcare sector in the state of Qatar:

- National Health Strategy 2; and
- Qatar National Vision 2030..

II. Regulatory Authorities

The healthcare sector in Qatar is primarily regulated by the Ministry of Public Health ("**MOPH**"), which is responsible for formulating and implementing health policy in the country, with a mandate to ensure provision of adequate and safe healthcare facilities to the country's population. MOPH carries out these functions in collaboration with the Supreme Council of Health ("**SCH**") and both these organizations directly or indirectly achieve the desirous goals with a close nexus to corporations like Hamad Medical Corporation ("**HMC**") and Primary Health Care Corporation ("**PHCC**").

Ministry of Public Health

The MOPH is entrusted with the responsibility of promulgating and overseeing the implementation of the national health policy and other healthcare-related regulatory frameworks in the country. The MOPH through its several departments carries out the supervision of the healthcare sector. The Department of Pharmacy and Drug Control in this regard is specifically entrusted with a role to ensure the quality of healthcare products and services in the country. It aims to create an outstanding, well-managed system that supports the national vision of wellness for all those living in the country.

Supreme Council of Health

SCH established through Qatar Emiri Decision No. 13 of 2009 is the custodian of the health of Qatar's people. Whereas MOPH is entrusted with practical aspects as well, SCH on the other hand is responsible for formulating the policy framework for the healthcare sector in the country. SCH is mandated with devising healthcare-related policies and programs with an aim to constantly improve the health and well-being of the state's people. SCH does not per se directly deal with the practical implementation of the policies itself but vests these tasks in the hand of public institutions like HMC and the private sector at large.

Hamad Medical Corporation

HMC is Qatar's premier non-profit healthcare provider came into being via Qatari Emiri decree in 1979. HMC is one of the leading hospital providers not only in Qatar but the Middle East. In addition to managing hospitals in the country, HMC operates both the national ambulance service and a home healthcare service.

Primary Healthcare Corporation

In recent times, Qatar has extensively focused on provision of primary healthcare to its population and in this regard, the creation of PHCC in the year 2008 was a major development.

PHCC is responsible for providing the people of Qatar with quality health care by operating and managing different health centers countrywide. Lately, PHCC is operating through approx. 28 healthcare centers situated in different regions of the country. PHCC, among other things, focuses on disease prevention, diagnosis, treatment and provision of long-term support to patients.

Qatar Council for Healthcare Practitioners

QHCP is an offshoot of MOPH's medical licensing department and was established independently in 2013 through Qatari Emiri decree No. 7 of 2013. More recently in the year 2019, through Qatar Emiri Decree No. 14 the QHCP has been reorganized as Department of Healthcare Professions. It is the sole authority in the state to regulate and license medical professionals. The newly created department functions through different sections namely registration and licensing section, fitness to practice section and accreditation section.

III. Regulatory Requirements for Companies under the Healthcare Law

There is no single codified legislation or set of rules laying down the regulatory requirements for companies under the Qatari Healthcare Law. To set up a commercial company, a regular commercial registration with the Ministry of Economy and Commerce ("MEC") is required. In addition, the SCH has set further requirements and procedures depending on the type of healthcare activities/services envisaged.

For any company to import and market its medical devices in Qatar an import permit is required which is issued by the MEC. The import permit by MEC is only issued to the local company / agent which apart from being a Qatari national is required to fulfill other custom-related requirements in order to obtain the permit e.g., registration with Qatar Customs Clearance Single Window. Only certain medical devices need an additional registration for import and use in Qatar. This includes any implantable medical devices, i.e., devices placed inside a human body during any medical intervention or surgical procedure such as pacemakers, implantable insulin pumps, hip implants, coronary stents, intraocular lenses etc. The import of medical devices into Qatar is managed by the MEC.

To get market access in Qatar, any medical device shall be authorized by one of the founding members of the Global Harmonization Task Force ("GHTF"). There is no internal classification system to bifurcate the types of medical devices for registration purposes, therefore, Qatar generally follows the EU classification model to classify the medical devices into risk-based classes e.g., classes I, IIa, IIb, III, and IV. Similarly, there is little or no information with regards to the post-market surveillance, however, it is safe to say that authorities expect any medical device being marketed in the country to conform with international standards with regards to the post-marketing surveillance and monitoring.

IV. Selecting a Local Representative

As foreign manufacturers require a local representative to import their medical devices to Qatar, the choice of selecting a suitable local representative, who will act as a liaison between the regulatory bodies and the device manufacturer company, becomes integral. Therefore, companies need to ensure that the selected representative is able to fulfil the required tasks

efficiently. The local representatives are responsible for carrying out all the related activities from the point of import to the circulation of the device in the market. These activities include but are not limited to obtaining an import permit, communicating with the regulatory bodies on a continuous basis to convince them of the efficacy and safety of the device, highlighting any adverse effect of the device to the regulatory bodies as part of the post-market surveillance and cooperating with agents, local companies and other entities for distribution and sale of the device within the state. Given that the local representative is the entity that represents the companies to the concerned authorities and other stakeholders e.g., customer, it is essential that a local representative is a well-established company who is aware of all the on-ground requirements, has adequate staffing and facilities to carry out all the aforementioned tasks.

V. Outlook

Despite there being checks and balances by the MEC on the import of medical devices, Qatar remains one of the least regulated markets with regard to import and marketing of medical devices in the region. Qatar, while recognizing in its policy documents that it does not have an extensive mechanism of regulating the medical devices, aims to develop a comprehensive regulatory mechanism for the medical device market. It is anticipated that in the coming future the role vested with MEC may be transferred to Department of Pharmacy and Drug Control which will likely entail much more requirements for the registration, import and marketing of medical devices in the country than what is currently required..

Oman

A. Introduction

Oman is located in the southeast of the Arabian Peninsula, sharing borders with the UAE, Saudi-Arabia and Yemen. Having overcome the Covid-19 crisis relatively well, it is now mainly profiting from the rise in oil prices which may boost government investments in the healthcare sector. Ever since Sultan Qaboos came into power in 1970, the development of a modern healthcare system has been one of the main goals of the Omani government. Sultan Haitham bin Tariq Al Said who became head of state in 2020 implemented the plan "Vision 2040" which among other aims to build a strong healthcare sector. In line with this goal, the tenth five-year plan aims to establish a culture of joint planning and implementation between governmental and private agencies proclaiming health to be everyone's responsibility. The healthcare system shall be characterized by decentralization, transparency, quality orientation, fairness and accountability. To ensure high-quality curative and preventive healthcare, Oman may profit from German health-tech providers

B. Market Analysis: Oman

The healthcare market in Oman, while being rather small compared to its neighboring countries, is unique due to its free public healthcare service for nationals and for foreign nationals working in the government sector. The healthcare industry in Oman is mainly run by the government with only a few private players in the market. Another big provider are companies in the oil and gas sector which provide medical support for their employees and families. Economic stagnation in response to years of low oil prices has limited government investment in the sector, resulting in several large-scale projects to be put on hold. In turn, this created opportunities for private investments in the healthcare and pharmaceuticals industry and in particular in the sector of specialized clinics focusing on long-term treatment of chronic illnesses such as diabetes and heart diseases encouraged and supported by the Omani government.

Another factor that turned the tide in favor of private investments in the Omani healthcare market are the much-needed general improvements in medical technology to keep up with the growing need of adequate healthcare. These are the development of Mobile Body Area Networks (MBAN), which monitor bodily functions (temperature, heart rate and rhythm, blood pressure, oxygen saturation levels) and transmit vital data to nursing stations and remote monitoring centers wirelessly. Another trend is Mobile Health (mHealth) technologies, which are using mobile communication devices (like smartphones, laptops) as well as wearable devices (e.g., smart watches) to collect and deliver healthcare information, allowing for the real-time monitoring of patient data and the timely and effective provision of patient care across distances. This market segment is likely to grow rather significantly due to the country's large and growing urban and young population that is relatively well-educated and informed when it comes to personal healthcare practices and products, particularly concerning app-based services.

The country's economic recovery due to rising oil prices and the lifting of Covid-19 restrictions is expected to lead to a consistent growth of Oman's healthcare and in particular the medical device market. In line with the Vision 2040, the economy will be diversified and government expenditures as well as the formation of public-private partnerships to further develop the healthcare system are expected to increase by about 9.1% annually. Until now, the market remains heavily reliant on imports (91.1%) as Oman still has a very limited domestic production of medical devices. Also, the domestic production is limited to non-tech-intensive consumables.

Oman especially wants to boost the implementation of modern technological solutions to foster efficiency in the healthcare sector which has already been notable in the digitalization of medical records. The Ministry of Health expressed interest in healthcare information technologies to be able to standardize operations as well as to establish interconnectivity among Oman's hospitals and clinics.

C. Legal Framework in the Oman Healthcare Sector

I. Healthcare Legislation

Oman's health care sector is subject to a number of legislative codifications. Different from other states in the GCC, medical devices have not become an independently regulated area of the law yet. However, under the heading of pharmaceuticals and drugs, medical devices have seen a recent recognition in Omani legislation which will see the medical device market in the Sultanate to be regulated more and more in the near future. Core instruments of such regulations have been so far:

- The Law on Regulation of Assuming the Profession of Pharmacists and Pharmaceutical Establishments enacted by Sultani Decree 35/2015 ("Law")
- The Executive Regulation of the Law enacted by Ministerial Decision 113/2020 of the Ministry of Health ("Regulation").

In light of the aforementioned, the Law only dedicates a limited focus on medical devices and leaves most of the regulatory specifications to the Regulation. The introduction of a regulated market for medical devices is a more recent phenomenon in the Sultanate then in other GCC states. Hence, market regulation is still evolving towards maturity and certain legislative and regulatory provisions are to be put to a practical test yet.

Besides the specific legislative and regulatory network, some other core documents and declarations of policy underpin the vital role of the healthcare sector in the Sultanate, e.g., the Vision Oman 2040 where health constitutes one of the 12 national priorities addressed by the Vision.

II. Regulatory Authorities

The main regulatory authority in Oman's healthcare sector is the Ministry of Health ("**MoH**") responsible for ensuring the availability of health care to the people of Oman. Within the MoH, the General Directorate for Pharmaceutical Affairs and Drug Control ("**GD**") assumes the central responsibility in relation to medical devices. The GD describes itself as the regulatory body which is responsible for assuring effective, safe and good quality drugs in Oman whether manufactured locally in Oman or exported from outside the Sultanate. After the most recent reforms, this regulatory competence also largely applies to medical products.

The Law further provides for one or more Technical Councils ("**TC**") to be established by a decision of the Minister of Health. Their core task is to review pharmaceuticals and medical products from a technical and scientific point and thus prepare the necessary assessment for the legal decisions based thereon.

III. Regulatory Requirements for the Companies

The healthcare legislation imposes certain requirements on the companies looking to import medical devices into the country. The Law defines "Medical Devices" as "any apparatus, means, material, device or product to be used singly or in combination with others including necessary programming for use on humans aiming at cure, personalization, prevention or easing of any illness or analysis or compensation from injuries or pregnancy regulation etc." The import of Medical Devices is subject to certain rules with regard to the import and registration which are provided briefly hereinbelow.

Import of Medical Devices

In general, the import of medical products into the Sultanate of Oman requires amongst others:

- Registration of the product in the Sultanate,
- Presentation of the purchase invoices from the producing company,
- For the product to be compliant with the data and specifications registered,
- To not be used before,
- (Upon request) to fulfil the requirements of temperatures for transport to the Sultanate, and
- Any further requirements issued by the GD.

The GD may exempt certain medical products from the registration requirements or may allow their import at eased conditions.

In case of a refusal to import Medical Devices, the respective medical devices must be returned to its country of origin by the importer or the agent or be destroyed within 45 days from serving the decision.

Furthermore, the importers or local agents are required to comply with certain storage, marketing and post-marketing surveillance requirements, such as the following:

- Store the medical products in accordance with the specifications of the manufacturer,
- Observe the special sales conditions and maintain a register to whom sales occurred, and
- Take care of corrective measures in case of any safety warnings.

Registration of Medical Devices

The application for the registration of a product is usually presented to the GD by an agent or legal representative which shall be accompanied by the following documentation:

- A copy of the written empowerment from the producer to the applying person,
- The identification labels accompanying the product in Arabic and English,
- An instruction manual for the product in Arabic and English,
- Any other documentation required from the GD (case to case basis).

Within 30 days from fulfilling all application requirements, the application will be transferred to the concerned TC, which will decide on the application within 60 days. Should there be no approval within these 60 days, the application is deemed refused. Such refusal does however not bar from a further application concerning the same product after one year. The TC may also suspend the decision of application to assure that the company adheres to the required quality standards.

Once approved by the TC, the GD has to register the medical product and issue a corresponding certificate with a validity of 5 years. Within 6 months from the end of these 5 years, the registration may be renewed for the same period and under the same conditions.

IV. Import Regulations especially Trade Agency

In order to import medical devices, each supplier or distributor must have a commercial agency certificate. Such certificates can only be obtained under the Omani Commercial Agencies Law enacted by Sultani Decree 26/1977 ("**CAL**").

The CAL provides that carrying out commercial agencies business or importing goods and offers of all types shall be prohibited inside the Sultanate for non-individuals or companies that do not meet the conditions set by the CAL, unless the goods are imported for personal use not for trading. Amongst the core requirements of such conditions is that individuals acting as trade agents must be Omani citizens and companies acting as trade agents must be ultimately held at least by 51% Omani individuals. Only such agents will be given the possibility to register a trade agency in the Sultanate.

A registered trade agency in Oman gives some distinctive legal protections to the agent, that cannot be modified to the agent's detriment by the agency contract. In between these protections is the duty of the principal to accept the renewal of an agency agreement with a limited term unless the principal can prove that the agent committed a mistake or breach of contract.

Unlike in other GCC countries, the Omani CAL does not grant exclusivity to the agent. However, even though Art. 10 of the CAL was repealed by the latest amendment of the law in 2014, the Omani courts tend to grant a considerable compensation to the agent in case of a termination or non-renewal by the principal which is not based on a severe breach of contract or duty by the agent. The use of sophisticated agency agreements outlining the detailed duties of the agent is therefore of utmost importance.

V. Outlook

Oman's regulatory landscape with regard to medical devices is in a constant evolution. This also has to be seen in the larger context of the COVID-19 pandemic and the recent change of government from Sultan Qaboos to Sultan Haitham. As one of the most dynamic markets with frequently underestimated potential, a glance on Omani matters and developments with regard to medical products can be very valuable to exporters.

Kuwait

A. Introduction

Kuwait is located in the northeast of the Arabian Peninsula, sharing borders with Iraq and Saudi Arabia. The country is largely a desert, and its economy is heavily based on oil production. Kuwait has one of the highest per capita incomes in the world and 102 billion barrels in oil reserves. The population of Kuwait currently stands at a 5-year low of 4.46 million. Having faced repeatedly high deficits, Kuwait's public finances have benefitted immensely from the climb in oil prices. This year, the government can look forward to its first fiscal surplus since 2014 of 8.8% of GDP. The turnaround will enable authorities to start recapitalizing the General Reserve Fund, which had been close to depletion. The country has one of the largest Sovereign Wealth Funds in the world, with an estimated USD 769 billion reserved for the "Future Generation". Being a welfare state, Kuwait spends most of its budget for salaries and substitutes. In this context, health tourism has been one of the major expenses the country funded for its citizens and their relatives. With the current trend of reorganization and tighter controls, the country invests heavily in its own healthcare sector.

B. Market Analysis: Kuwait

Kuwait has one of the most significant healthcare expenditures in the GCC and is the fourth-most obese country in the world. The public healthcare sector accounts for more than 80% of the healthcare spending in the country.

Kuwaitis suffer from high rates of obesity, diabetes, and cancer. Despite a young population, diseases strain health and public finances. Kuwait is a welfare state where free medical treatments are provided in government hospitals, including sending patients for treatment abroad. The country's healthcare expenditure budgeted for 2021-2022 amounted to a massive USD 8.9 billion. Kuwait's Ministry of Health is the owner, operator, regulator, and financer of

most healthcare services, pharmaceuticals purchased, and medical equipment. The government operates 28 general and specialized hospitals.

The Ministry of Health and the Ministry of Public Works allocated around USD 5 billion for developing and expanding nine operating hospitals (five general hospitals and four specialized hospitals) within the next ten years. Around USD 540 million is reserved for developing and expanding specialty hospitals. The goal is to add 5,400 beds, 150 operating rooms, and 500 outpatient clinics to the current 7,095 hospital beds countrywide. In addition, the USD 1.1 billion (KD 304 million) Sheikh Jaber Al-Ahmed Al-Sabah Hospital, which was inaugurated in 2020 as a Covid-19 emergency hospital, and the USD 1.1 billion New Jahra Hospital, which is expected to be fully operational in the coming months, will add a total of another 2,402 beds. According to the World Bank, Kuwait has two hospital beds per 1,000 people, representing a significant undersupply.

The country has a well-established primary care network of more than 100 polyclinics distributed within Kuwait's six governates (Ahmadi, Al-Asimah, Farwaniya, Hawalli, Jahra, and Mubarak Al-Kabeer).

The private sector is expected to grow moderately in the coming years, with private firms estimated to account for 15-20% of healthcare spending. Sixteen private hospitals (totaling 1,200 hospital beds) provide private medical services in Kuwait. Another 1,800 beds are expected to be added within the next few years in private hospitals.

Medical Devices

Kuwait's medical device market has a limited number of prominent international players who hold the lion's share, and the market is completely import-driven. In terms of revenue, the market has grown by a CAGR of 10% from 2012 to 2017, driven by rising sales of orthopedic appliances, hearing aids, radiotherapy equipment, operating tables, and medical furniture. The market focuses on laboratory and diagnostic equipment, surgical instruments, and general supplies in oncology, radiology, orthopedics, cardiology, trauma, and other fields. There is no manufacturing facility for medical devices in Kuwait.

New medical device registration, sale, and marketing regulations ensure more alignment with international standards and reflect increased quality control. Thus, German products are in high demand.

The market is expected to register a double-digit CAGR of 11.0%, driven by private sector investments, infrastructure development, and rising chronic diseases. It is scheduled for offline sales to continue to dominate the market share, but this will decrease in the next five years.

C. Legal Framework in the Kuwait Healthcare Sector

I. Healthcare Legislation

The healthcare sector in Kuwait is regulated through different legal instruments which ensures the adequate provision of healthcare services to the residents. With regard to medical devices, the major regulation is the newly issued Ministerial Decision 13/2022. In general, the major legislative and policy instruments forming the healthcare regulatory framework in Kuwait are the following:

- Kuwait Ministerial Decision 13/2022 on the Registration and Trading of Medical Devices and Supplies;
- Kuwait Law No. 70/2020 on the Practice of the Medical and Paramedical Professions, the Rights of Patients and Health Facilities;
- Ministerial Resolution No. 302/80 issuing the Guidelines for Registration of Pharmaceutical Products;
- Ministerial Resolution No. 99/201, issuing the Guidelines for Registration of Non-Classified Products and Medical Devices;
- Ministerial Resolution No. 532/02, issuing Guidelines for Registration of Nutritional Supplements; and
- Kuwait Vision 2035.

The above-stated legislative and policy instruments coupled with directives issued by authorities from time to time forms the healthcare sector in the state of Kuwait.

II. Regulatory Authorities

The healthcare sector in Kuwait is predominately regulated and supervised by the Ministry of Health ("**MOH**") and the departments made thereunder. The MOH supervises the sector in a structured manner through several of its departments which are responsible for carrying out the activities including but not limited to licensing and registering of Medical Products and Devices, inspection and supervision of healthcare products and facilities, research and development of the healthcare sector, training and capacity building of the healthcare industry etc. Whereas, the majority of regulatory functions are carried out by the public sector departments established under the MOH, however, the establishments like Health Assurance Hospitals Company ("**DHAMAN**") who have been established under the Public Private Partnership model also carry out a chunk of regulatory functions by undertaking certain supervisory functions within their domain. Hereinbelow, we will briefly analyze the primary healthcare regulators and their functions in the Kuwait's healthcare sector:

MOH

MOH is primarily responsible for the provision and constant improvement of the healthcare facilities in the state of Kuwait. The MOH ensures that residents of Kuwait are provided with the state of art healthcare facilities at par with the international standards. MOH does not only carry out the policy-making function but also implements the State's healthcare policy through its departments. MOH has developed an integrated system for all the health information systems to ensure seamless delivery of quality healthcare services to the state's population.

The Department of Registration and Control of Medicinal and Botanical Drugs

The drug and food control administration lies with the Department of Registration and Control of Medicinal and Botanical Drugs ("**Drug Control Department**"). The Drug Control Department in Kuwait is responsible for the registration of medical and herbal preparations, nutritional supplements and medical devices in addition to veterinary preparations. The primary authority

for allowing the import or release of medical devices from the customs rests with the Drug Control Department.

DHAMAN

The Health Assurance Hospitals Company ("**DHAMAN**") was established in 2015 as the first public-private-partnership healthcare organization in the Middle East to pursue the national development plan under the Kuwait Vision 2035. 24% of DHAMAN's shares are owned by governmental bodies whereas the rest is owned by the private sector. DHAMAN works to provide a full spectrum of integrated healthcare services by leading a holistic network of primary healthcare centers and hospitals as well as other healthcare-related ancillary services.

III. Regulatory Requirements for Companies under the Healthcare Law

As mentioned above, the requirements with regard to the registration and trading of medical devices in the state of Kuwait are laid down under Ministerial Decision No. 13/2022 which came into effect in January 2022. The regulations under this new Decision are more detailed than earlier regulations and ensure alignment with international regulations and standards such as the EU Medical Devices Regulation. In general, medical devices cannot be imported, marketed and sold in Kuwait without being duly registered by the local agent or distributor of the manufacturer with the Pharmaceutical & Herbal Medicines Registration and Control Administration Department of the MOH.

Registration of Medical Devices

The registration requirements depend on the level of potential hazard inherent in the type of medical device concerned which, in turn, depends on the intended use and the technology utilized. Medical devices are divided into four classes of products depending on their potential when hazardous. Such classification corresponds with the classification of the EU Medical Devices Regulation whereas Class A represents the low-risk devices and Class D devices with the highest risk. The applicants are required to fill in the application form coupled with the dossier of the required documents which is usually submitted physically with the authorities. The application is required to be submitted through an appointed local representative only. The state of Kuwait only allows the import of new medical devices, therefore, the import of pre-owned and used medical devices is strictly forbidden. The public sector being the major consumer of these devices strictly requests brand-new devices when issuing a tender. Once the registration has been undertaken it will be valid for a period of five years

Import and registration of medical devices in the state require a local representative / agent in Kuwait. This local agent is also required to be registered with the authorities in order to affect the import of medical devices into the country.

Registration of the agent in Kuwait

The selection of an agent is an important step for the companies looking to import medical devices in Kuwait as the local agent is predominately responsible for representing the company and its products to the relevant local authorities. As in other GCC states, companies are advised that when selecting a local agent, they should execute a bespoke agency agreement which

should clearly highlight the rights and obligations of the parties. The agency agreement shall be precise when it comes to conferring rights upon the agent. Among other things, the parties shall ensure that the agent is duly registered with the local authorities. In addition, the agent must hold a license allowing him to conduct the import and sale of medical devices in the country.

Registration of the Manufacturer

Similar to the separate registration of an agent, there is a mechanism for registration of the Manufacturers as well. The requirements for such registrations are as follows:

- An original and notarized agency certificate between the manufacturer and the agent in Kuwait, whereby the certificate states that the agent in Kuwait is the exclusive agent for that company and the respective medical devices;
- An original and notarized manufacturing license for the manufacturer, issued by the responsible authority in the country of origin;
- An original and authenticated GMP certificate of conformity with the health authorities in the country of origin; and
- A comprehensive file about the factory and the company, including all data from equipment information, production lines, products, certificates obtained by the factory, plans, control processes, quality and others.

Bahrain

A. Introduction

The Kingdom of Bahrain ("**Bahrain**" or "**Kingdom**") has one of the oldest healthcare sectors in the Gulf region dating back to 1902 when American missionaries established the first modern hospital in the region. However, owing to an oil boom in the mid-20th century, the country has been able to further develop its healthcare sector to meet the needs of its population of attaining better healthcare service. Lately, Bahrain has taken steps to introduce greater private sector involvement in the healthcare sector, which led many foreign healthcare companies to market their services and products in the Kingdom. Bahrain has seen a sharp rise in imports alone in 2019/2020 – especially in regard to medical devices. Bahrain imported medical devices worth more than BD 30 million. The trend is set to grow, given the promised investment by the Bahraini government in the coming years.

Companies, who are looking to enter the healthcare market in the Kingdom, are to follow a strict regulatory process before they can import, promote or sell their products freely. Bahrain has a comprehensive regulatory mechanism in place which spans from the pre-entry of the medical product in the country to its post-market surveillance to ensure that the residents of the Kingdom are getting access to the best medical products in line with international standards.

B. Market Analysis: Bahrain

Bahrain is already home to prominent healthcare training institutions, providing solid foundations for further healthcare investment, such as The Royal College of Surgeons in Ireland, the College of Health & Sport Sciences, and the Arabian Gulf University.

Bahrain has a young (with a median of 32,5 years), educated population with the region's highest private sector engagement. Bahrain's population offers a highly skilled local and global workforce with one of the best human capital developments in the Middle East and North Africa (MENA) according to the World Bank.

Ranked the first in MENA for ICT readiness (information and communications technology) by the World Economic Forum, Bahrain offers competitive and affordable ICT services in the region.

In April 2020 the first telemedicine platform "Doctori" was launched. The app, which was created by a local start-up, allows patients to connect with a health professional via video for a scheduled checkup or an urgent consultation. It also has the possibility of receiving prescriptions or consultation reports.

Doctori is the first telemedicine platform in Bahrain to be licensed by the National Health Regulatory Authority (NHRA).

By the end of 2018 the National Health Insurance Law (NHIL) came into force. Now health insurance coverage had been made compulsory for almost all citizens, residents and visitors. This health insurance coverage is financed via a fund, into which all insured persons covered by the program have to pay their contributions. The employer of foreign nationals is paying the insurance contributions on their behalf, whereas the contributions for Bahraini nationals are being paid by the government. All persons covered by this insurance are able to see doctors in government hospitals/clinics and health care centers. The level of covered care depends on the insurance level the employer has chosen. Therefore, many expatriates opt for an additional private health insurance. Bahraini nationals can go for an additional health insurance package via the fund (subsidized by the government), which then covers treatment at private sector facilities.

The latest project is the implementation of the "Sehati" card, which will be launched nationwide and given to anyone covered by the National Insurance. The Sehati Card is a chipcard, that stores all medical data of the insured. It simplifies the transfer of individual medical information and personal data between different hospitals and physicians, especially between government and private facilities. There are several purposes for the Sehati Card. One is to give patients the freedom to choose their health provider. But it might also boost the competition in the health sector, as it will be easier to switch to a private health facility then it was before.

Bahrain Pharma (established 2020, EDB) is the first large-scale fully operational pharmaceutical manufacturer in Bahrain. Bahrain Pharma's manufacturing will currently be focused on vegetarian soft gel capsules and syrups as well as nutraceuticals. They have started with two production lines with a total annual production capacity of 9 billion soft gel capsules and 25 million syrup bottles with the potential to expand production capacity to three additional production lines of soft gel capsules.

Import of Medical Devices

According to the National Health Regulatory Authority (NHRA), Bahrain imported medical devices for more than BD 30 million in 2019.

The National Health Regulatory Authority (NHRA) (https://www.nhra.bh/) is an independent regulatory body established in 2010 under Law No. 38 of 2009. NHRA's mission is to regulate the provision of healthcare in Bahrain and ensure appropriateness, continuity, efficiency and safety in delivering health services, both in the governmental and private sector. Medical devices regulation in NHRA grants all suppliers an approval to import medical devices in the Kingdom of Bahrain based on international standards (nine international ISO standards also translated into Arabic to be recognized globally).

The online pre-application system for procuring devices (OFOQ) is a web-based software developed by Customs Affairs - Ministry of Interior (MOI) allowing all the governmental sectors to grant pre-approvals of shipments requests submitted by importers, on one page to better monitor and control all shipments accessing the Kingdom of Bahrain ports. All medical devices with HS (harmonized system) codes regulated by NHRA must obtain a pre-approval by first submitting the required documents on OFOQ system.

Medical Devices Regulation Guidelines can be seen on the webpage of the NHRA (https://www.nhra.bh/Departments/MDR/).

C. Legal Framework in the Bahrain Healthcare Sector

I. Healthcare Legislation

Healthcare legislation in the Kingdom is an amalgamation of several legislative, policy and guiding instruments which together form a coherent set of principles to ensure the safety and standards of medical devices and products being imported into the country. Among others, the major legislative instruments are the following:

- Bahrain Law No. 38/2009 on the Establishment of the National Health Regulatory Authority;
- Bahrain Decree-Law No. 21/2015 on Private Health Facilities; and
- Bahrain Decision No. 12/2015 Issuing the Regulations on Drugs Registration System in the National Health Regulatory Authority.
- In addition to the abovementioned legislative instruments, the following are the policy instruments steering the legal framework with regard to medical devices in the Kingdom:
- National Health Plan 2016-25;
- NHRA Strategy 2016-20; and
- Bahrain Economic vision 2030.

II. Regulatory Authorities

The health care sector in Bahrain is primarily regulated by the Ministry of Health ("MoH"), which is responsible for formulating health policy in the country, with a mandate to ensure the health and safety of the kingdom's population. In pursuit of its objective to provide a lifetime access to the Kingdom's residents of quality healthcare services and products, the MoH collaborates with the National Health Regulatory Authority ("NHRA") and the Supreme Council of Health ("SCH"). Hereinbelow, we will briefly analyze the formation and functions of the aforementioned regulatory authorities.

Ministry of Health

The MOH being a primary regulator operates under four guiding principles which are sustainability, accessibility, equity and quality. Through these principles the MOH strives for maintaining high public healthcare standards through promotion and prevention activities,

integrating services across the health care system through stakeholders such as NHRA and SCH and by improving healthcare services via governance and policy making. MOH runs a broad system of hospitals, clinics and specialized centers that are free of charge for citizens.

NHRA

NHRA was established vide Law No. 38 of 2009, to supervise and license the healthcare facilities across both public and private sectors. The law mandates NHRA to oversee matters such as registration and pricing of medicines and medical products, licensing of pharmaceutical factories, patient complaint processes, and a validation system for medical errors, as well as an approval process for medical research activities. NHRA while exercising its mandate has formulated comprehensive programs for registration, marketing and importation of medical products into the Kingdom while adhering to the policy objectives to maintain the quality and safety standards in the healthcare industry.

SCH

SCH was established pursuant to Royal Decree No. 5 of 2013 with a mandate to set up Bahrain's national health care strategy. SCH is in charge of strategic planning and in collaboration with other stakeholders it formulates policies aimed at improving and developing the healthcare sector in the country.

III. Regulatory Requirements for Companies under the Healthcare Law

The companies wishing to get their medical products into Bahrain must follow sets of various regulations and guidelines regarding the registration, importation and marketing of medical devices in the country. Through these regulations and guidelines, NHRA has set different requirements with regard to the classification of the medical devices, registration and importation of medical devices.

The guidance issued by the NHRA covers the most important aspects of medical devices and the registration process necessary to place a device on the national market. The medical devices under these guidelines have been bifurcated into three categories namely "medical device", "combined medical device", and "in-vitro diagnostics". The definition of a medical device is similar to the definition used in EU regulations, whereas, combined medical device definition includes all devices containing specific additional components, such as pharmaceutical products or biological materials. An IVD covers all devices intended for the examination of a specimen derived from the human body to obtain information on the state of the human organism, monitor the effectiveness of therapeutic measures, identify abnormalities or check compatibility. The requirements imposed by NHRA for classification, registration and importation are briefly discussed hereinbelow:

IV. Classification, Registration & Import of Medical Device

Medical devices in Bahrain are classified based on the level of risk inherent in the given device. The risk is calculated based on the following factors:

- intended use of the device;

- the duration of contact with the body; and
- the degree of invasiveness.

NHRA has issued Medical Device Classification Guidelines ("**Classification Guidelines**"). Classification Guidelines are intended to assist the companies through the classification procedure. As classification of the devices is a foremost step for the companies given it is a requirement for both the registration and importation of devices in the Kingdom, therefore companies are advised to obtain a classification certificate before applying for the registration or importation of the same. Medical devices are classified into the classes ranging from class III, II b, II a and I, wherein, class III entails the highest risk, hence, more regulatory checks, and class I being classified as low-risk devices which are comparatively subject to lesser regulatory checks.

Process for Classification of the Medical Device

The application for classification is initiated by booking an appointment using NHRA's online system for submitting the required documents. Once an appointment is booked and required documents are submitted, the documents are evaluated by NHRA and in case a device is classified as a medical device the applicant receives a classification letter which can be used for importation and registration requests. In order to obtain a classification letter, among other things, the applicant is required to submit the following documents:

- Free Sale Certificate or Registration Certificate issued from the competent authority in the country of origin which classifies the product as a medical device;
- Free Sale Certificate or Registration Certificate issued from one of the referenced countries;
- Quality Assurance Certificate (e.g., ISO 13485, CE Mark, FDA);
- Product intended use/ Artwork issued by the manufacturer; and
- Declaration from the manufacturer showing the active ingredients percentage which should match with the percentage for drug classification.

Registration of Medical Devices

Bahrain's registration procedure was first introduced in 2015, while the current regulatory framework was adopted in 2018. The registration process is intended to assess compliance with safety and performance requirements set forth by applicable regulations and standards. The NHRA additionally emphasizes that the guidance has been developed on the basis of similar documents issued by reputable regulating authorities, such as US FDA, British MHRA or Australian TGA, in an attempt to implement global standards and approaches to medical device regulations to improve regulations on the national level.

Registration of medical devices in the Kingdom is highly regulated and the NHRA has developed a set of requirements which is contained in the Medical Devices Registration Guidelines ("Registration Guidelines"). Though the registration of medical devices in Bahrain only commenced in 2015, however, since 2018, the whole registration framework has been rejuvenated. The mechanism for registration of the medical devices is envisaged as per the

international standards of quality and safety and the Registration Guidelines have been adopted from the regulations of renowned global health authorities such as SFDA, FDA, MHRA, TGA. Foreign companies wishing to put their products in the local market can only register their devices through an authorized representative, who is solely authorized to apply for the registration with NHRA. As matter of principle, all medical devices are bound to be registered irrespective of their risk classification. Once registered, all medical devices are published along with their authorized representatives on NHRA's website.

Process of Registration

In order to apply for medical device registration, the authorized representative is required to book an appointment using the "Appointy" system for submitting the registration form along with the required documents. The documents are to be submitted electronically which are then reviewed by the NHRA team which normally takes 6 to 8 working weeks to give its decision. Once the NHRA team is satisfied then a registration certificate is issued with a validity of minimum 1 year up to 5 years based on the validity of the submitted Quality Assurance Certificate. The authorized representative, among others, is required to submit the following documents for registration:

- Medical device registration form filled, signed and stamped by the authorized representative;
- Technical details such as user manual, catalogue, and service manual;
- Artwork i.e., label of the medical device;
- Agreement or authorization letter issued by the legal manufacturer to the authorized representative for the distribution of the applied medical device/s in the Kingdom of Bahrain;
- Letter issued by the legal manufacturer stating the physical manufacturers and authorized distributors of the medical device/s with their respective addresses;
- Instruction for use such as leaflet and material safety data sheet;
- List of countries the medical device has been marketed in, issued by the legal manufacturer;
- Field safety notice records affecting the Bahraini market;
- Quality Management System Certificate (QMS) - ISO 13485 from the physical manufacturer;
- Quality Assurance Certificate (QAC) - CE directive 93/42/EEC or FDA;
- If the legal manufacturer is different than the physical manufacturer, a relationship letter between the legal and physical manufacturers issued by the legal manufacturer is required; and
- Free Sale Certificate (FSC) or Certificate of foreign government issued by the regulatory authority of the country of origin or a reference country.

The companies may require submitting certain other documents depending on the classification of the medical device.

Importation of Medical Devices

Since 2016, all medical devices with the HS code listed under ministry code 2251 (NHRA medical devices) must hold an online license before being cleared to enter the Kingdom. Importation licensing is a distinct process for the registration of the device itself and is normally carried out in parallel to the registration. NHRA regulates the importation of medical devices Class II and III only, which is mapped to the HS codes and listed on NHRA website to facilitate the importation approval for importers. Companies are required to obtain a pre-approval for all medical devices with HS codes regulated by NHRA by submitting the required documents on OFOQ system; a web-based software developed by Customs Affairs - Ministry of Interior (**MOI**) allowing all the governmental sectors to grant pre-approvals of shipments requests submitted by importers.

The NHRA for the purposes of import of the medical devices has set certain requirements in the Online Medical Device Importation Approval Guideline ("**Import Guidelines**"). These guidelines are intended to highlight the process and requirements to get the preapproval of medical devices importation through OFOQ system. Under the Import Guidelines, importation of medical devices can only be done through an authorized representative, who must possess commercial registration allowing him to import such products. It is further required that a request on "**OFOQ**" must be submitted before shipping the item in order to grant pre-approval before shipment arrives at Bahrain port. However, if the medical device is already registered in NHRA, pre-approval is granted by attaching the valid NHRA license along with the invoice. Companies must be aware that importation of used/refurbished medical device is prohibited in the Kingdom.

Process of Obtaining a Pre-Approval

The process defined under the import guidelines is an automated one wherein importer should initially have a username and a password from the customs headquarter, by contacting them by email. Once an account is established all the required documents and information are submitted through the portal and upon review of the supplied information, approval is granted or rejected by the authorities.

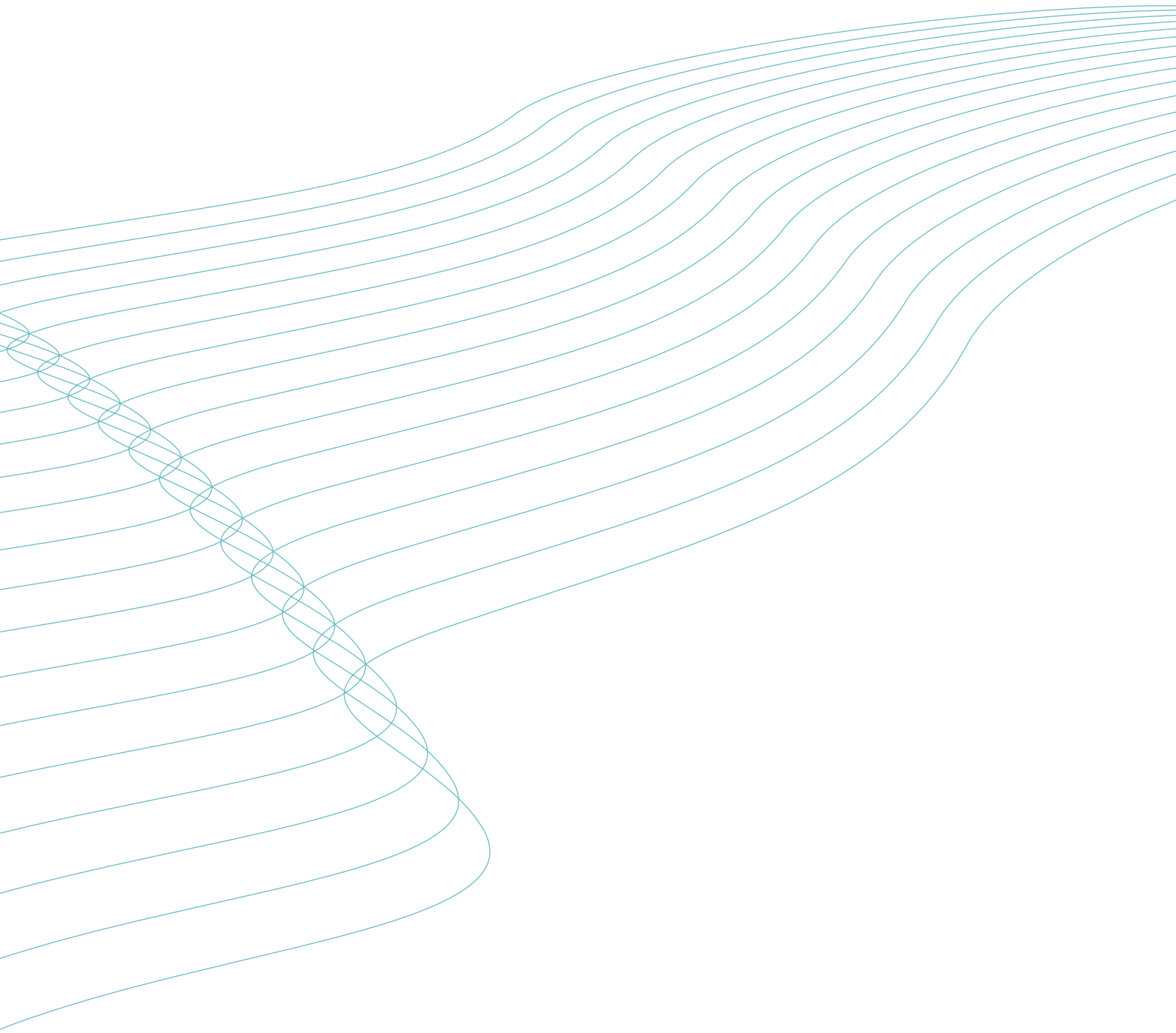
Documents Required for the Import of Medical Devices

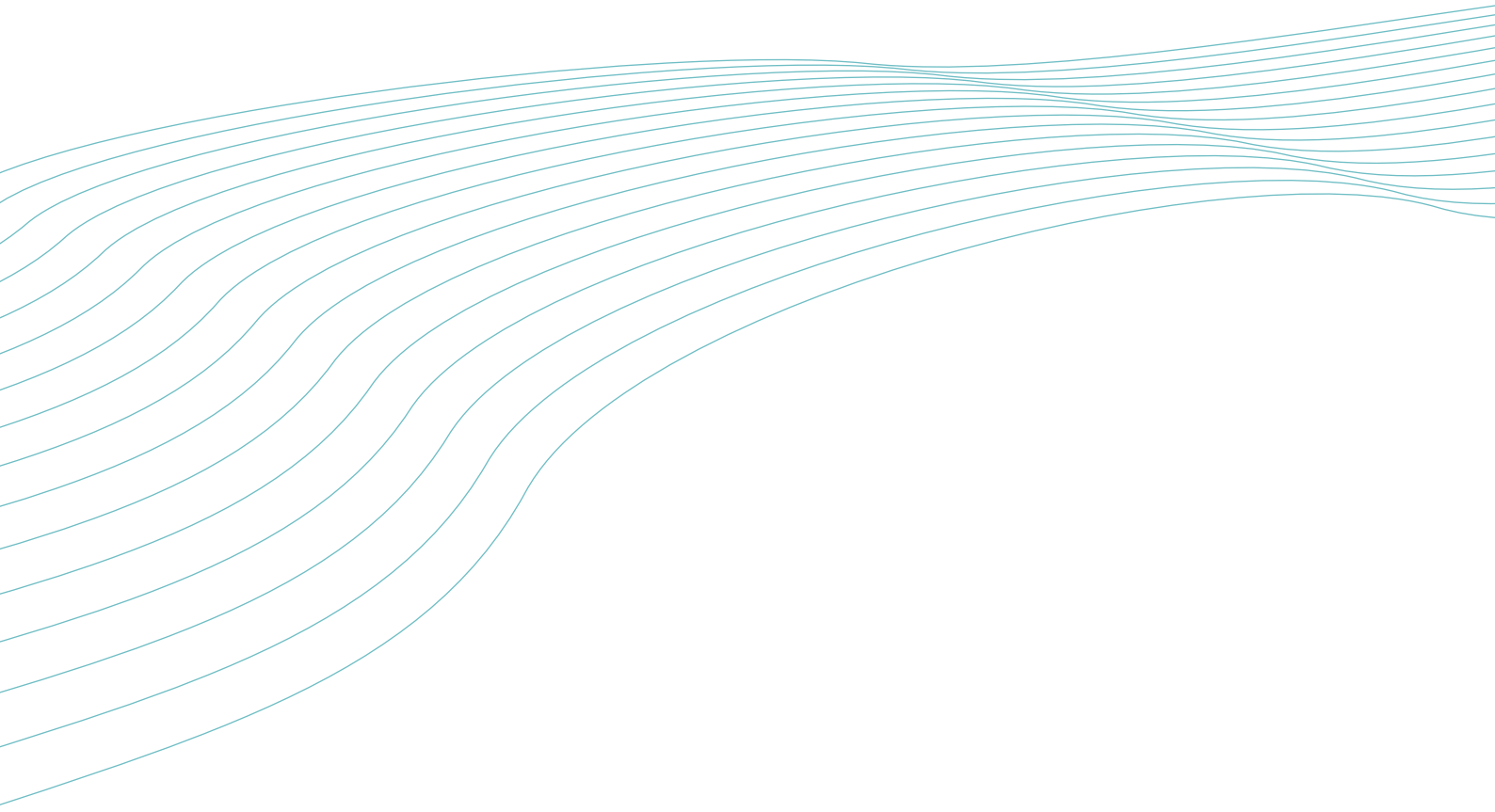
The companies, among other things, are required to submit the following documents in order to import medical devices into the Kingdom:

- Invoice including HS Code/ manufacturer name & country of origin;
- Product quality documents, (e.g., foreign government FDA, CE);
- NHRA medical devices registration license, if not available then the below information/ documents;
- Quality Assurance Certificate (CE);
- Quality Management System (ISO 13485);
- ISO 13485 for medical devices class I;
- Catalog containing the imported product code / Ref No. as mentioned in the invoice; and
- Label of the medical device should include the name of the legal manufacturer.

Note:

Note:





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