
KING & SPALDING

measure

The Middle East Periodic Bulletin

Spring 2018

2017 Country Review:
Kingdom of Saudi Arabia

A Guide to Saudi Real
Estate Law for Foreign
Developers

Initial Coin Offerings in
the United Arab Emirates

Keep it Confidential:
Use and Sale of Online
Customer and User
Information

Health Matters: Issues and
Updates on the Regional
Healthcare Sector



Foreword

*Welcome to the Spring 2018 issue of **measure**, King & Spalding's Middle East periodic newsletter. Following a host of legal developments in the region over recent months, we look at the following in this issue:*

- Noting that this is the first issue of MEasure to be published in 2018, Nabil Issa and Saud Al-Dawsari take a look at some of the key legal developments in the Kingdom of Saudi Arabia in 2017.
- Moustafa Said and Nabil Issa take a look at the real estate and other laws in the Kingdom of Saudi Arabia that foreign developers must bear in mind when considering a real estate investment in the Kingdom.
- Against the backdrop of the increasing prominence of cryptocurrencies globally and the commensurate rise in initial coin offerings or ICOs, James Stull and Hamed Afzal explore the use and development of ICOs in the United Arab Emirates.
- Osama Audi and Ruslan Sulaimanov examine the legal framework applicable to the processing of personal and/or confidential information in the United Arab Emirates.
- Osama Audi and Yousef Farsakh discuss the key points to bear in mind when structuring and undertaking a healthcare-related corporate transaction in the Middle East.

Our Middle East team continues to serve our clients in creatively and innovatively structuring transactions to help meet our clients' objectives. Recognition we have received in the past several months includes:

- receiving 29 individual rankings and being highly recognised in 13 practice groups throughout the Middle East – *Chambers Global 2018*;
- winning the Africa Deal of the Year for the Africa Finance Corporation Sukuk, Corporate Finance Deal of the Year for Delivery Hero and Cross Border Deal of the Year for our Souqalmaal/Riyad Taqnia deal – *Islamic Finance News Awards 2017*;
- being selected as the best firm for fund structuring and onshore law firm of the year for the third year in a row – *MENA Fund Manager 2018*; and
- winning the deal of the year award for Jadwa REIT – *Asian-MENA Counsel Awards 2018*.

We hope you find this issue useful and informative, and we look forward to helping you keep abreast of further developments in our region.



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Middle East depicted on a coin

GENERAL CORPORATE

2017 Country Review: Kingdom of Saudi Arabia



Since the inception of the 2030 Vision and the National Transformation Program 2020, the Kingdom of Saudi Arabia (**Kingdom**) has taken significant strides towards achieving the goals of both plans. In 2017, the Kingdom further focused on its legal and regulatory terrain with the goals of liberalizing the economy, increasing non-oil revenues and improving investors' confidence. These changes are also key aspects of wider social and economic reforms aimed at meeting the needs and expectations of a young population. It is widely noted in the press that women will be permitted to obtain driver's licenses from summer 2018. Potential privatizations have been announced in the healthcare, education, airport, military, grain silo and power sectors. The Saudi Arabian government has announced a number of real estate and tourism megaprojects in the Kingdom. Parties are closely watching the anticipated partial IPO of Saudi Aramco.

We review some of the most important measures of 2017 in the various sectors of the economy.

NEW DECREE TO PROTECT MINORITY SHAREHOLDERS IN LLCs AND CJSC

In April 2017, His Excellency the Saudi Minister of Commerce and Investment issued a new Ministerial Decree (**Decree**) aimed at enhancing the protection of the rights of minority shareholders of unlisted joint stock and the limited liability companies. The Decree supplements the Saudi Companies Law, which was amended in 2016.

According to the Ministry of Commerce and Investment (**MCI**), the Decree reflects MCI's interest in improving and promoting the business and investment environment in the Kingdom, and in enabling the private sector to contribute to the realization of the Kingdom's Vision 2030 strategic objectives.

The majority of the Decree's directives relate to disclosure requirements of business and contractual transactions in which the directors of the unlisted joint stock and the limited liability companies have an interest. For instance, the Decree stipulates that the Board of Directors must obtain the approval of the Ordinary General Assembly for any business or contractual transaction in which one of the directors has a direct or indirect interest.

In 2017, the Kingdom further focused on its legal and regulatory terrain with the goals of liberalizing the economy, increasing non-oil revenues and improving investors' confidence.

The Decree also mandates that the director who has such interest must disclose to the Board the interest, its extent, and any related financial and non-financial benefits with respect to such interest and abstain from voting on the transaction.

In addition to disclosure requirements, the Decree imposes other obligations on the management of a company aimed specifically to protect minority shareholders. For instance, the Decree stipulates that management must obtain the approval of the company's shareholders prior to the sale of more than 50% of the company's shares. Moreover, the Decree requires the Board to take into consideration matters that the minority shareholders – owning at least 5% shares – wish to raise during the Ordinary General Assembly.

The Decree also introduces new regulations on limited liability companies. For example, it states that a limited liability company cannot introduce a new shareholder without the unanimous consent of all existing shareholders.

NEW M&A RULES

On 19 October 2017, Saudi Arabia's market regulator, the Capital Market Authority (**CMA**), approved updated regulations for mergers and acquisitions (**M&As**) among Saudi-listed companies, effective upon publication. The new rules update the M&A rules that were enacted in 2007.

The new rules are meant to encourage M&As among Tadawul-listed companies. They include the regulation of the acquisition through the general assembly, as well as controls over the relevant sales or purchases, the approach, the mandatory offers and disclosure requirements.

The amendment continues to apply to any (i) purchase

or sale of voting shares in a Saudi-listed company resulting in ownership or control of 10% or more of the shares, and (ii) offer to purchase voting shares in such a company, if the shares sought to be acquired would increase ownership to 10% or more.

It is also important to note that the new rules extend to a new category of transaction called “Private Sale and Purchase Transactions”. These are defined as a sale or purchase of voting shares in a Saudi-listed company negotiated between the offeror and selling shareholders without making an offer or involving the other shareholders or directors of the target.

NEW COMMERCIAL COURTS IN THREE CITIES

The Kingdom launched new commercial courts in three cities to facilitate investment as the country continues to diversify its economy. The courts started operating on 2 September 2017, and were officially launched by the Minister of Justice in a special ceremony in October. According to the Minister of Justice, the commercial courts would help enhance the business environment, encourage and motivate investment in the Kingdom, and boost economic development in line with the objectives of Saudi Vision 2030.

The three commercial courts are located in Riyadh, Jeddah and Dammam, with specialized commercial chambers within public courts in a number of Saudi cities. The jurisdiction of the courts includes primary and ancillary commercial disputes between merchants, claims made against merchants as a result of their primary or ancillary commercial activities, disputes between shareholders in companies, and bankruptcy claims and receivership orders.

THE KINGDOM PASSES THE IMPLEMENTING REGULATIONS OF THE 2012 ARBITRATION LAW

On 22 May 2017, the Kingdom passed the Implementing Regulations of the 2012 Arbitration Law. The regulations came into force on 9 June 2017. The implementation is considered a significant stride in enhancing the business environment, making it more attractive to foreign investors and bringing it closer to international norms. The implementing regulations supplement and significantly clarify the 2012 Arbitration Law, which replaced the

outdated 1983 arbitration law. The law applies to Saudi-based arbitrations and is modelled on the UNCITRAL Model Law on International Commercial Arbitration. The regulations also strengthen the position of the Saudi Center for Commercial Arbitration, which was established in 2014.

The regulations have several key transformative features. For instance, they allow for electronic service of summons to arbitrate. This is a major positive change as there were no formal ways for enacting service of process in Saudi Arabia except through diplomatic means. The regulations also allow for the arbitral tribunal’s discretion in permitting the intervention or joinder of a third party in the arbitration proceedings. Third-party joinder in international arbitration has been a hot topic discussed by many arbitration commentators recently.

THE SAUDI ARABIAN GENERAL INVESTMENT AUTHORITY (SAGIA) ISSUES NEW INVESTORS’ MANUAL

SAGIA governs and regulates foreign investment in the Kingdom. The agency has been extremely active in 2017. Its semi-annual report for 2017 shows a significant 133% increase in the value of investment projects compared with the same period in 2016. The surge in the figures – from SR 1.39 billion in 2016 to SR 3.25 billion this year – comes as SAGIA issued 158 new licenses in the first half of 2017, up from 127 in the first six months of 2016.

The rise in both the value of investments and the number of licenses comes as SAGIA has recently implemented a series of initiatives to enhance its role as an advocate for investors. In May 2017, SAGIA issued a new investors’ manual allowing for automated licensing procedures and significantly lower documentation requirements for licensing. The average number of required documents declined from 21 to two.

SAGIA’s 2017 report shows that China topped the list of countries with the most companies investing in Saudi Arabia in 2017, with projects valued at SR 254 million. The United States and the Netherlands were ranked second and third, with investments valued at SAR 187 million and SAR 180 million, respectively.

NEW DRAFT REGULATIONS FOR PRIVATE HEALTHCARE PROVIDERS UNDER PUBLIC CONSULTATION

Revamping the health sectors in the Kingdom is a critical objective of the Saudi Vision 2030 and the National Transformation Program 2020 (**NTP 2020**). The Saudi plans for the health sector have been welcomed by investors as they set out aims and objectives for more private involvement. Indeed, one of the strategic objectives of the NTP 2020 is to “[i]ncrease private sector share of spending through alternative financing methods and service provision”. In preparation for this growth, the Ministry of Health (**MoH**) has issued an amendment to its private healthcare regulations and opened these amendments for public consultation. The MoH is also preparing to release an investors’ guide to accompany the new amendments.

While many expected that the amendment would liberalize the sector for foreign investors, rules pertaining to foreign investment under the new amendment remain unchanged. Foreign investment continues to be restricted to hospitals. Moreover, we have been advised there is an MoH circular that continues to provide that foreign investment is restricted to hospitals with more than 100 beds. All other types of private healthcare establishments such as clinics and laboratories must be 100% Saudi owned.



FOREIGN OWNERSHIP IN THE EDUCATION SECTOR

In August 2017, unofficial sources reported that the health and education sectors were going to be open for 100% foreign ownership. As discussed above, the MoH’s new draft regulations have refuted this claim. With respect to foreign ownership in the education sector, SAGIA issued its latest manual, which opened the sector for 100% foreign ownership. Lastly, we note we have been advised that foreign investment in K-12 schools will soon become permissible following expected approval from the Ministry of Education.

SAUDI COUNCIL OF MINISTERS APPROVES 100% FOREIGN OWNERSHIP OF COMPANIES IN ENGINEERING SECTOR

The Kingdom approved the issuance of licenses allowing foreign companies 100% ownership in the engineering services and engineering consultancy sector.

Under the policy, foreign investors will now have the flexibility to structure their company optimally to benefit from opportunities in the Saudi market. They may seek 100% ownership or operate through a joint venture with a local investor.

The decision by the Saudi Council of Ministers sets conditions on the 100% ownership model: (i) the company must be established no less than 10 years in its country of origin, and (ii) the company or one of its subsidiaries operating in the field of engineering services must be present in at least four countries.

The decision authorizes the Board of Directors of the SAGIA to exempt any of the abovementioned conditions if the Board determines that the exemption will serve the interest of the Kingdom. The decision also mandates that the Board’s exemption authority must be in accordance with general criteria established by the Board, which shall be clear, publicly accessible and non-discriminatory.

The previous investment limit under the joint venture model was up to 75%.

The Saudi Council of Ministers’ decision opens yet another sector to greater foreign investment as part of wide-ranging economic reforms. In 2016, the Council agreed to allow 100% foreign ownership of companies

The Kingdom approved the issuance of licenses allowing foreign companies 100% ownership in the engineering services and engineering consultancy sector.

in the wholesale and retail sectors. The Dow Chemical Company became the first company to receive such license from the Government of Saudi Arabia.

THE KINGDOM TO INTRODUCE VALUE ADDED TAX IN 2018; ISSUES VAT LAW AND DRAFT IMPLEMENTING REGULATIONS

The tax regime in the Kingdom saw a transformative change in 2017. Most importantly, the Kingdom introduced the Value Added Tax (**VAT**) which went into effect on 1 January 2018. In May 2017, the General Authority of Zakat and Tax (**GAZT**) issued the VAT tax law, which was ultimately approved by the Shoura Council in July of the same year. Thereafter, GAZT issued the draft VAT implementing regulations on its website for public consultation purposes. The VAT draft implementing regulations include details on the application of VAT and would provide guidance for the Kingdom's taxpayers to help them in getting ready for VAT.

The VAT is an indirect tax imposed on a broad range of goods and services that are bought and sold by businesses, with a few exceptions. The VAT will be set at a standard rate of 5%, although some goods and services will be exempt or zero rated. For instance, food supplies, education services and healthcare services will all be subject to VAT at 5%. Exempt services include the supply of financial services. The implementing regulations include zero-rated supplies too, such as the export of goods from the Kingdom and the supply of medicine and medical equipment.

We note that the VAT structure is complex and will probably require taxpayers some time to fully apprehend it. Businesses, however, are advised to start reviewing the law, as implementation is approaching quickly.

NEW EXPATRIATE DEPENDENT FEE INSTITUTED

Another development in the tax regime is the new levy on expatriates' dependents. The fees came into effect on 1

July 2017. The Saudi General Directorate of Passports and Expatriate Affairs said levy fees on expatriates' dependents include all nationalities with no exceptions. Expatriates are now required to clear the fees before they are able to obtain exit/re-entry visas for their family members and domestic employees. The fee schedule is as follows:

- 2017: SAR 100 per month per dependent
- 2018: SAR 200 per month per dependent
- 2019: SAR 300 per month per dependent
- 2020: SAR 400 per month per dependent

SAMA TO SAUDIZE INSURANCE JOBS

In February 2017, the Saudi Arabian Monetary Agency (**SAMA**) obliged insurance companies to Saudize 100% of certain jobs by July. The list covered all claims management insurance, including claims branches and reception centres, as well as the Saudization of all jobs related to customer care departments and jobs related to complaints reception within the different sectors of insurance. In July, SAMA declared that it will not extend the deadline and violators may be sanctioned.

CMA AMENDS THE AUTHORIZED PERSONS REGULATIONS AND THE GLOSSARY OF DEFINED TERMS USED IN THE REGULATIONS AND RULES OF THE CAPITAL MARKET

The CMA amended some of its regulations. According to the CMA, the amendments are intended "to develop private equity and venture capital investments, and support the assets management industry in Saudi Arabia, and in line with the National Transformation Program and Saudi Arabia's Vision 2030."

The majority of amendments are to the glossary of definitions in the Authorized Person Regulation, including the definition of "Sophisticated Investor", "Professional Investor" and "Institution".

REMOVAL OF EXPORT RESTRICTIONS ON REBAR STEEL AND CEMENT

The Kingdom removed some outdated export restrictions that affect the domestic manufacturers of construction material. In July, MCI issued a statement to cancel all export duties on steel products and cement for two years. The decision to rescind the ban comes in the wake of the slowdown in the construction industry following the decline in oil prices, which had led the government to cut back on its infrastructure budget. The Ministry of Finance reduced the allocations for infrastructure and transportation by 62% in its 2016 budget, to US\$6.37 billion.

FOCUS ON SME SECTOR

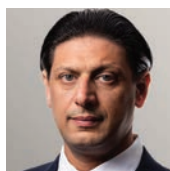
In 2017, the Saudi Arabian government announced numerous initiatives to further encourage the venture capital and SME industries. Such initiatives include the Public Investment Fund announcing a fund of more than US\$1 billion to invest in funds focusing on the SME and venture capital sectors. The SME Authority has also announced a thorough review of the laws and regulations of Saudi Arabia impacting the venture capital and private equity industries in Saudi Arabia.

CONCLUSION

Saudi Arabia is undergoing dramatic shifts as it works to evolve from an economy that has largely been focused on oil. New regulations and initiatives were announced on an almost weekly basis in 2017. Parties are now closely watching the announced potential privatizations and planned PPPs in Saudi Arabia.



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REAL ESTATE

*A Guide to Saudi
Real Estate Law
for Foreign
Developers*



Saudi Arabia's real estate sector looks to benefit from a number of significant recent developments. These include the Capital Market Authority's (CMA's) introduction of real estate investment trusts, the 'white land' tax on undeveloped properties and increased government stimulus as part of the National Transformation Plan – Saudi Arabian Vision 2030.

With comparative returns improving, many UAE-based developers are increasingly looking towards the Kingdom of Saudi Arabia for their next development project. Often the initial entry takes the form of an investment or real estate joint venture with a Saudi Arabian partner that owns land and has experience of, and a sales distribution channel in, the local market.

Although Saudi Arabian real estate law shares many features with the equivalent real estate laws of the UAE, there are a number of differences that warrant further consideration by potential developers in Saudi Arabia.

The right of non-GCC nationals to own land in real estate is governed by The Foreign Ownership of Real Estate Regulation (Royal Decree No. M/15 dated 17/4/1421 H (corresponding to 19 July 2000 G)). Non-Saudi Arabian corporate investors may own real estate required for the conduct of their professional, technical or economic activities, subject to obtaining approval of the licensing authority. Similar to the UAE, a company must be wholly owned by Saudi Arabian nationals for the company to be treated as a Saudi Arabian national for this purpose. If the

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license allows the purchase of buildings or land for the construction of buildings for investment purposes, the project size must be at least 30 million Saudi riyals, and investment in the form of real estate development must occur within five years of purchase of the real estate.

This means that foreign developers must obtain a license from the Saudi Arabian General Investment Authority (SAGIA) to engage in real estate development in Saudi Arabia. A foreign company wishing to invest in real estate in Saudi Arabia will typically need to establish a Saudi Arabian entity to acquire ownership of, or a leasehold interest in, real estate in Saudi Arabia. Foreign shareholders may also invest in Saudi Arabian real estate outside the cities of Makkah and Madina through a real estate investment fund. Companies which have invested in this manner include Solidere and Gulf Related.

Non-GCC national individuals may own property in Saudi Arabia if they are resident in Saudi Arabia and obtain a permit from the Ministry of Interior.

According to the Regulation for Real Estate Ownership by the Citizens of the GCC States in the Member States of the Cooperation Council for the Purpose of Residence, (Housing) and Investment, GCC nationals are permitted to own built real estate and lands for the purpose of housing or investment, without the need to obtain a SAGIA license. If the real estate is raw land, its building or utilisation must be completed within four years from the date of registering it in the name of the owner. The owner may dispose of the built real estate at any time. However, if it is raw land, the owner may dispose of it as from the date of completing its building or utilisation or after the lapse of four years after the date of registering it in its name.

Saudi Arabia does not have a title system with a Government-backed guarantee of title. Instead, titles are issued by the competent notary public in each city and are recorded in a real estate register for this purpose. The Realty in Kind Registration Law (Royal Decree No. 6 of 9/2143 H, corresponding to 24/2/2004 G) (Property Registration Law) provides that a registration recorded in the real estate register cannot be contested unless there has been a breach of Shari'ah principles or a fraud or

forgery has taken place to obtain ownership, and after the lapse of specified periods for objection as set out in the Property Registration Law.

The notary public department has recently introduced an electronic title deeds system under the new Shamil system. This was implemented in Riyadh and is being progressively rolled out in other cities. The benefit of an electronic system is that the process to effect title transfers is being expedited as the notary public has to carry out fewer checks to verify the ownership of the property. Where a property is greater than 10,000 square metres, the parties have to obtain an approval from a special committee of the notary public department for such transfer.

The Property Registration Law requires registration of leases which exceed five years in the real estate register to be enforceable against third parties. Notwithstanding this requirement, this system has not yet been implemented by the relevant governmental authorities.

Similar to the UAE, the title registration system used in the Kingdom of Saudi Arabia does not record secondary interests in land in favour of third parties, such as leases, sub-leases, rights of way, occupancy, easements, restrictive covenants, liens, charges and other encumbrances, etc. This means that extensive due diligence is required with respect to the foregoing matters.

The law relating to multiple ownership of units within a building is based on an antiquated system (the System of Ownership of Units, Estates, Units, Apartments and their Sorting, issued by Royal Decree No. 5 on 11/2/1423 H (corresponding to 24/4/2002 G)). The Government has recognised that there is a need to update this law to account for the complexity of multi-owner apartment buildings and mixed-use projects such as combined hotel and residential developments. One of the key considerations is the enforceability of collecting service charges. Another key issue is the management arrangements for multi-owner units. A recent development has been the incorporation of an owners association with independent legal personality.

The general rule is that non-Saudi Arabian nationals may not obtain title, easement or use of real estate located



within the city limits of the holy cities of Makkah and Madina. Non-Saudi Arabian nationals may lease real estate within Makkah and Madina for a period not exceeding two years, renewable for similar periods. This restriction is strictly enforced. For example, the CMA will not allow non-Saudi Arabian investors to invest in Makkah and Madina through real estate funds, even though this is allowed for projects in other cities in Saudi Arabia. However, we note there have been recent press announcements on foreign investors potentially investing in the holy cities through a sukuk structure.

Saudi Arabia has traditionally not had a mortgage law, and therefore banks and finance companies typically lent money against an ifragh – pursuant to which a borrower would transfer title of the relevant secured real estate to the lender or a nominee on behalf of the lender to be held as security.

However, a mortgage law was issued, namely Registered Real Estate Mortgage Law (Royal Decree No. M/49 dated 13/08/1433 H (corresponding to 2 July 2012)). However, the Saudi Arabian Monetary Authority (SAMA) has recently issued circular number 381000089828 dated 26/08/1438 H (corresponding to 22/05/2017 G) directing all banks and finance companies in Saudi Arabia to use mortgages (as opposed to an ifragh) when taking security over real estate, replace their interest in the

secured real estate presently held in their name (or in the name of a nominee on their behalf) with mortgages over the relevant real estate within three years, and inform their clients of the same, and advise SAMA of instances where any notary public refuses to register a mortgage over real estate in favour of a bank or finance company.

The regulations for the sale of real estate units put in place a regulatory regime for the sale of 'Real Estate Units' off-plan (being the sale prior to the creation of an individual title for the Real Estate Unit) in the Kingdom of Saudi Arabia. The regime effectively requires a developer to apply for a licence from a committee at the Ministry of Housing known as 'WAFI' (established pursuant to Resolution of Council of Ministers No. 73 dated 12/03/1430H) to act as a developer for the purpose of selling off-plan.

In summary, the Off-Plan Regulations (Resolution of Council of Ministers No. 73 dated 12/03/1430 H (corresponding to 09/03/2009 G)), Resolution of Council of Ministers No. 47 issued 04/02/1434 H (corresponding to 18/12/2012 G), and Regulatory Procedural Guidelines for the Off-Plan Sales of Real Estate Units, issued by the Decree of His Excellency the Minister of Commerce and Investment No. 983/8/267, dated 02/02/1431 H (corresponding to 18/01/2012 G) cover the following key elements: the establishment by WAFI of a developer and off-plan sales registry, the licensing of developers to sell off-plan, the approval of the project for off-plan sales, the approval of sales documentation, the establishment of escrow accounts for the depositing of purchaser payments and financier advances, the approval of brokers, the oversight of construction by WAFI, and the taking over of the project by WAFI in the event of default by the developer. The license to sell off-plan is intended to be issued by WAFI for each 'Project' and must be obtained before the developer commences any marketing or sales of the Real Estate Units.

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CAPITAL MARKETS

Initial Coin Offerings in the United Arab Emirates

ICOs, also referred to as initial token offerings, initial public coin offerings, token launches and token sales, are a method through which start-ups and other companies can raise capital.

BACKGROUND

Against the backdrop of the increasing prominence of cryptocurrencies globally, initial coin offerings or ICOs are becoming commensurately popular as a capital-raising method. ICOs, essentially a method of crowdfunding undertaken through the use of blockchain technology, reportedly helped raise US\$4.5 billion in 2017, nearly 20 times more than in 2016. Whilst a common criticism directed towards ICOs has been the lack of regulation, regulators in numerous jurisdictions have thus far been making an effort to communicate guidance to market participants. Moreover, regulators have, in some instances, clarified the application of existing regulation to ICOs, or have expressed an intention to create new or broaden existing regulatory frameworks to apply to ICOs. In particular, a number of regulators (particularly in the US) have begun to seek enforcement against ICOs that do not comply with securities laws, undermining some of the early ICO exuberance that perhaps “utility tokens” would escape regulation as securities. In addition, regulators of exchanges around the world ranging from commodities exchanges to currency exchanges have begun assessing what rules should apply to the trading of coins or tokens, creating additional uncertainty about regulatory status and whether the exchange regulators and securities regulators will come to consistent conclusions about how to treat ICOs.

At the same time that many countries have reacted with a stated or implicit desire to curb ICOs, a number of countries have embraced the potential of blockchain and sought to develop regimes that will address some of the

core concerns about ICOs but also foster the appropriate growth of their use.

In this context, we examine the approach taken thus far by relevant authorities in the United Arab Emirates (the UAE) to ICOs.

WHAT IS AN ICO?

ICOs, also referred to as initial token offerings, initial public coin offerings, token launches and token sales, are a method through which start-ups and other companies can raise capital. In an ICO, investors participating in the offering receive digital tokens (Tokens) in exchange for fiat currencies (required to be transferred to an “online wallet” of the issuer) or cryptocurrencies (required to be transferred to one or more designated addresses (an online reference for cryptocurrencies similar to an account number)). Tokens can be designed to represent any right that the issuer defines. Some tokens represent “utilities” such as passes to access services, while others represent the holder’s right of benefit or performance with respect to the issuer; for example, pursuant to its terms, a Token could represent the right to a profit or payment upon the issuer achieving certain business milestones (much like the dividend on a security) or a right of use (of, for example, a particular service offered by the issuer or a loyalty rewards program, which is similar to a gift card program). In contrast to shares offered in a traditional initial public offering (IPO), Tokens do not typically represent an ownership interest in the issuer.

ICOs are typically launched or announced through cryptocurrency forums, websites or other online channels, though with increasing securities enforcement, public advertising may scale back, at least in the near term. Through the relevant channel(s), the issuer will typically provide access online to a white paper (the Whitepaper) describing the business or project and the key terms of the ICO (i.e. the structure and key features of the tokens offered, economic terms, subscription details, etc.), and providing information on the status of the project and key team members involved. In addition to the White paper, the ICO documentation may also include a token purchase agreement, which will set out the terms and conditions

applicable to the tokens. On completion of the ICO, the Tokens will be distributed to the participating investors' designated addresses or online wallets.

The underlying technology of the Tokens is based on blockchain (an electronic distributed ledger, in which transactions are protocolled in a documented and reproducible way without a central authority), which is maintained by a network of participants and computers. Similar to shares offered in an IPO, Tokens are typically tradable on virtual currency exchanges, creating a secondary Token market.

REGULATORY CONSIDERATIONS – AN INTERNATIONAL PERSPECTIVE

Bearing in mind that blockchain platforms such as Ethereum operate without borders, for an ICO and its applicable participants to be in compliance with applicable regulatory requirements, it may be necessary to structure the ICO to be compliant with regulations across multiple jurisdictions.

At the time of writing, the general regulatory theme in most jurisdictions has been that ICOs may fall within the scope of existing regulatory regimes, and that regulators are watching this space closely. In jurisdictions with established regulatory and securities laws such as the United States, the Securities and Exchange Commission (SEC) has signalled an increasing concern with ICOs and has taken enforcement action against a number of ICO issuers, stating in a recent case that an ICO was an offering of securities without registration or available exemption, notwithstanding that the relevant Tokens sold in the concerned ICO were designed to have a utility function. Since then, the SEC has made numerous public comments and brought a series of actions to demonstrate its commitment to applying securities laws to tokens and discounting the utility role of a token that more broadly has the appearance of a utility. In addition, SEC action chills

the ability of issuers to promote the expected availability of independent public trading. Thus, while private placements of tokens to wealthy “accredited” investors are possible, the path to broad trading or liquidity is now obscure. In the UK, the Financial Conduct Authority has issued a consumer warning on ICOs, has asked for feedback from market participants on the legal and regulatory risks associated with ICOs, and has commented that depending on how they are structured, ICOs may fall within the existing regulatory regime.

ICOS IN THE UNITED ARAB EMIRATES

UAE (onshore)

In the UAE, there is currently no specific regulation applicable to ICOs, albeit there are certain licensing requirements which apply where a right in an underlying commodity in which trading does require a license is offered (such as, for example, gold) and certain regulators have issued guidance with respect to ICOs.

There was, however, some uncertainty regarding the status of virtual currencies when the UAE Central Bank (the Central Bank) published a new licensing framework for stored value facilities offering certain in January 2017, which stated “All Virtual Currencies (and transactions thereof) are prohibited”. The Central Bank later confirmed that the regulations “do not cover Virtual Currency” and “do not apply to Bitcoin or other cryptocurrencies, currency exchanges, or underlying technology such as blockchain”. It was, however, noted that new regulations will follow, and so it is expected that specific regulation will be issued in this area by the Central Bank in the near future.

On 4 February 2018, the Emirates Securities and Commodities Authority (the SCA), which regulates the conduct of securities business in the UAE, for the first time offered guidance related to cryptocurrencies and ICOs. The SCA issued a circular highlighting for potential

Similar to shares offered in an IPO, Tokens are typically tradable on virtual currency exchanges, creating a secondary Token market.

investors certain risks associated with “digital, token-based fundraising activities or investment schemes” covering ICOs, token presales and token crowdsales, including that:

- Some ICOs are not regulated and thus may be subject to fraud risks;
- ICOs may be issued abroad, and therefore are subject to foreign laws and regulations that can be difficult to verify. Tracking and recovering funds in case of ICO collapse may prove to be extremely difficult in practice;
- ICO trading on the secondary market is subject to opaque, volatile pricing and insufficient liquidity;
- Many investors, especially retail, may not be able to comprehend the risks, costs and expected returns arising from ICO investments; and
- ICO information made available to investors may be unaudited or incomplete and may present a given investment case in an unbalanced and misleading manner.

The SCA circular reiterated, however, that it does not recognize, regulate or supervise any ICO presently and that ICO investments are not offered legal or regulatory protection. It said that investors involved in ICO investments are doing so at their own risk.

In November 2016, the Supreme Legislation Committee for the Government of Dubai, in cooperation with the Dubai Electronic Security Center, announced discussions on future legislation related to cryptocurrencies. As a result, specific regulations concerning the Emirate of Dubai could also be issued.



In the absence of specific regulation and official guidance, other than the SCA circular and a statement reportedly made by the governor of the Central Bank on the high risks to investors and money laundering risks posed by cryptocurrencies, it is difficult to ascertain with any degree of certainty the extent to which ICOs could fall within the scope of the existing regulatory regime in the UAE. For example, it is possible that the Promoting and Arranging Regulations (the PIRs), published by SCA on 10 January 2017, apply to the promotion of Tokens in the UAE. Under the PIRs, unless an exemption applies, the promotion of financial products to persons in the UAE requires an SCA licence, for which an onshore UAE business presence is required. Whilst exemptions include promoting to institutional investors and licensed financial institutions and promotions on a reverse solicitation basis, no such exemption exists for retail or high-net-worth individuals. Furthermore, “financial products” is broadly defined to include securities, commodity contracts, derivatives or structured products.

Dubai International Financial Centre

In the Dubai International Financial Centre, the Dubai Financial Services Authority (DFSA) has issued a warning statement to investors that cryptocurrency investments should be treated as high risk. The DFSA also clarified that it does not regulate ICOs and would not license firms undertaking such activities.

ABU DHABI GLOBAL MARKET

In the Abu Dhabi Global Market (ADGM), the Financial Services Regulatory Authority (FSRA) issued guidance in October 2017 on ICOs and cryptocurrencies which clarifies that, whilst ICOs and cryptocurrencies would not be regulated in and of themselves, the FSRA will take a substance-over-form approach, such that certain components of an ICO may fall within existing regulation, such as operating an exchange, or offering securities or units in a fund. The FSRA also confirmed that many aspects of ICOs may not be regulated activities, and urged caution by investors.

On 11 February 2018, the FSRA announced that it is reviewing and considering the development of a robust, risk-appropriate regulatory framework to regulate and supervise activities of virtual currency exchanges and intermediaries.

CONCLUSION

Whilst ICOs represent a significant and innovative new frontier for capital raisings, participants should exercise caution. In the UAE, as in many other jurisdictions, whilst no specific ICO regulation is in place, elements of ICOs could certainly fall within the existing regulatory perimeter. As such, a detailed analysis of the regulatory framework is necessary to ensure compliance, particularly in the context of a cross-border ICO. Moreover, irrespective of the ICO and Token structure and components, the issuing company should in all circumstances ensure that it provides investors with sufficient and accurate information to enable them to make an informed investment decision.

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The background features a series of concentric, curved lines in shades of purple, orange, and yellow, creating a sense of motion and depth. Overlaid on this is a network of white nodes connected by thin white lines, resembling a digital or data network.

CORPORATE REGULATORY

Keep It Confidential: Use and Sale of Online Customer and User Information

As is the case in many jurisdictions around the world, data protection laws and the use and protection of confidential customer information continue to be subject to much discussion and debate in the Middle East, with relatively little clear-cut guidance as to what is/isn't permitted. Advocates for privacy and operators of social media platforms and e-commerce websites have approached the subject from different perspectives, with one group focusing almost exclusively on privacy concerns and the other seeking to balance such concerns against the customer/user experiences and compliance with requests of governmental authorities.

In the United Arab Emirates, there is a dearth of official guidance and/or case law from the authorities and courts as to what constitutes legitimate processing and use of personal and/or confidential information (e.g. customer names and addresses, telephone numbers, credit card and/or bank account details, details of locations of customers making orders, and the preferences of such customers) and whether a distinction should be made between the use and/or processing of such information by private parties or by the relevant authorities in the United Arab Emirates. The lack of reliable guidance is partially driven by the fact that customers and private individuals resident in the United Arab Emirates have either been unaware of the complex issues relating to confidential personal data or have taken a generally relaxed approach when it comes to challenging parties that process and use their personal data.

Under the UAE Constitution, citizens of the United Arab Emirates have a general right to privacy, described as follows: “[F]reedom of corresponding through the post, telegraph or other means of communication and the secrecy thereof shall be guaranteed in accordance with the law”. Most commentators agree that this gives rise to a general right to privacy for individuals. However, that right is limited to citizens of the UAE, a group reported as 8% to 12% of the total population actually living in the UAE. The UAE Constitution does not contain a corresponding protection for non-UAE citizens.

The UAE Cybercrime Law also prohibits the invasion of privacy of an individual, by means of a computer network and/or electronic information system and/or information technology, without the individual's consent, unless otherwise authorised by law. The Cybercrime Law further prohibits disclosing confidential information obtained in the course of, or because of, work, by means of any computer network, website or information technology. Thus, anyone who uses, without authorization, any computer network, website or information technology to disclose confidential information which was obtained in the course of doing business/work commits an offence pursuant to the Cybercrime Law.

Accordingly, e-commerce businesses and other online platforms (including social media platforms) that aggregate and sell the confidential information of their customers/users to third parties, without the consent of such customers/users, are potentially acting in violation of the Cybercrime Law. What is unclear is whether general consent through click-through agreements on the websites of e-commerce businesses and social media platforms is sufficient to constitute consent.

In addition, to date, there is a lack of guidance as to whether a general disclosure of customer/user information at the request of a public authority would be permitted pursuant to the Cyber Crimes Law. However, the exemptions used under other less recent UAE laws may be used as an interpretive guide to determining what is meant by “authorised by law”.

In the United Arab Emirates, there is a dearth of official guidance and/or case law from the authorities and courts as to what constitutes legitimate processing and use of personal and/or confidential information.



Pursuant to delegated powers from the Ruler, the UAE Privacy of Consumer Information Policy was issued on 31 May 2005. This applies to all telecommunications licensees and to any entity that has access to personal information made available to it for purposes of providing telecommunications services.

The aim of the policy is to ensure that the information of telecommunications consumers in the UAE is protected. Accordingly, whilst it is only a policy, it provides helpful guidance on how consumer information should be treated. Consumer information includes personal data about the consumer such as information requested for ordering services, voice/data and SMS content and transmissions, call and usage patterns, and any other information derived from a consumer's use of telecommunications services.

The policy provides that licensees must obtain a consumer's prior consent before sharing any consumer information with their affiliates and other third parties not directly involved in the provision of the telecommunications services ordered by customers.

Article 379 of the UAE Penal Code also provides that it is a criminal offence to use a third party's information without consent for one's own or another's advantage where that information was gained as a result of the disclosing party's profession/work, unless such disclosure or use is permitted by law.

In relation to requests for disclosure from governmental authorities, whilst the phrase *"unless such disclosure or use is permitted by law"* provides a clear exemption from prosecution in the event that the *"law"* permits such disclosure, there is a lack of official guidance or case law on whether the phrase *"permitted by law"* would capture a general request for access to information by public authorities. While there is a lack of official guidance or case law in this regard, our view is that it is likely that such requests would fall within a *"disclosure or use permitted by law"*, particularly if a specific judicial order and/or warrant requiring disclosure was issued.

In any event, disclosures to public authorities are typically permitted, as under Article 377 of the Penal Code and Clause 3 of the Privacy of Consumer Information Policy, the requirement to obtain an individual's written consent can be waived where the following conditions are met: (a) a UAE official/public authority has required the transfer of the data to it and (b) the transfer serves public interests or national security. In addition, the ad hoc provision of information on specific individuals to a public authority made from time to time to assist with investigations most likely falls within the consent already provided by customers.

It is worth bearing in mind that Article 282 of the UAE Civil Code provides that a company will be responsible for any act taken by it which causes harm to others and that such an act shall be compensated. Accordingly, e-commerce companies and social media platforms should give due consideration to whether they have received the prior consent of their customers prior to sharing any confidential customer/user information with third parties.

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CORPORATE - LIFE SCIENCE

*Health Matters: Issues and
Updates on the Regional
Healthcare Sector*

Investment in the Middle Eastern healthcare sector – one of the key sectors targeted by both corporates and private equity funds – has continued its significant growth. The sector has witnessed continued consolidation, wide anticipation of massive regional privatization programs, exploration of new models of provision (such as managed care) and, interestingly, the development of a number of regional providers. The growth opportunities have been in general provision and have been more pronounced in specialisms such as oncology/haematology, psychiatry, in vitro fertilization, gastroenterology, neurosurgery and elective cosmetic surgery, some of which were previously and continue to be underserved.

In addition to healthcare provision, there has been growth in supporting sectors as disparate as laboratories, pharmaceutical and medical device manufacturing and sales, telemedicine (though limited in many ways by an unclear regulatory environment), and the manufacturing and distribution of medical supplies and equipment. The profile of payors has also seen a shift, with regional governments (which in many cases act as regulator, provider and payor) requiring mandatory health insurance for residents as part of their ambition to act as regulators alone, with the provider and payor role shifting to the private sector.

The growth in private sector healthcare provision has been further spurred by privatization programs announced or at various stages of progress in a number of countries in the Gulf Cooperation Council (GCC). In Saudi Arabia, Kuwait and Oman, plans are underway to create public-private partnerships (PPPs) to manage and operate portions of each government's significant portfolio of government-owned hospitals and clinics. By way of

example, the World Health Organization estimates that the governments in these three countries own more than 50%, 80% and 92% of hospital beds, respectively. As each of their respective privatization programs – many of which are in early stages – accelerate, we anticipate significant opportunities for investment.

In addition, the United Arab Emirates (UAE) has continued its program of privatizations and PPPs. with Abu Dhabi National Oil Company (ADNOC) and Abu Dhabi-based NMC Healthcare, a component company of the FTSE 100, recently announced they had entered into a management agreement to manage ADNOC's Ruwais hospital in the Al Dhafra region.

While the Middle Eastern healthcare sector presents many opportunities for investment, investors should be cognizant of a number of common issues, summarized below, when contemplating entering into or expanding their footprint in the sector.

1. CONSIDER FOREIGN OWNERSHIP RESTRICTIONS IN THE TARGET SECTOR.

The right investment structure can make the difference between a successful transaction and a transaction that fails to achieve regulatory approvals and ultimately fails. Many of the structures which investors have utilised to access the healthcare sector seek to decrease enforceability risk for transaction documentation (e.g. shareholders' agreements and sale and purchase agreements) and enable parties to access investments in activities which are heavily regulated.

One of the key regulatory hurdles in the region is foreign ownership. Many of the countries in the GCC restrict non-GCC national investment in the healthcare sector. In addition, most of the countries in the GCC restrict, to some extent, investment by other GCC nationals in the healthcare sector. The level and type of investment that is permitted varies from country to country and from sector to sector. For example, foreign ownership in Saudi Arabia is only permitted for hospitals (as defined in the relevant regulations and subject to the approval of the Ministry of Health), while polyclinics, clinics, radiology centres, medical laboratories, same-day

While the Middle Eastern healthcare sector presents many opportunities for investment, investors should be cognizant of a number of common issues

In most of the large markets in Saudi Arabia (e.g. Riyadh and Jeddah), the Ministry of Health will only issue a license to a foreign-owned hospital if such hospital has more than a given number of beds,

surgery centres, opticians, dental clinics, physiotherapy centres and pharmacies must be wholly owned by Saudi Arabian nationals with no foreign entity permitted to have ownership in the capital structure.

Our experience has been that in most of the large markets in Saudi Arabia (e.g. Riyadh and Jeddah), the Ministry of Health will only issue a license to a foreign-owned hospital if such hospital has more than a given number of beds, although we are aware of examples where non-Saudis have been permitted to invest in hospitals with fewer beds. For instance, the limitation may not apply to hospitals which are in more-remote areas of Saudi Arabia. In addition, the Ministry of Health generally takes a more restrictive approach on the development of new hospitals in markets that it believes are saturated.

In addition, the Ministry has recently published an update to the Private Healthcare Institutions Regulations which explicitly permits non-GCC nationals to own companies which operate (i.e. not own) polyclinics, clinics, radiology centres, etc., provided that such operating company qualifies with a number of requirements and has otherwise been approved by the Ministry. Non-GCC nationals can also own entities providing ancillary services such as waste management, IT support and sterilisation services. Consistent with Saudi Arabia's desire to encourage in-country manufacturing, parties manufacturing medical devices and pharmaceutical products (and directly selling such manufactured medical devices and pharmaceutical products) can also be non-GCC national owned, though they will have to comply with the Saudi Arabian General Investment Authority's requirements in order to receive a foreign investment license for manufacturing.

2. USE THE RIGHT INVESTMENT STRUCTURE, TAKING INTO CONSIDERATION FOREIGN OWNERSHIP RESTRICTIONS AND ENFORCEABILITY.

The structures that corporates and private equity utilise to invest in the healthcare sector vary. In the UAE, Kuwait and Saudi Arabia, amongst others, some investors still utilise illegal nominee arrangements to circumvent foreign ownership restrictions and put themselves at significant risk for criminal and civil sanction. Foreign investors should consider alternative, enforceable structures to access the healthcare sector. For example, to date some foreigners have accessed the Saudi Arabian healthcare sector by investing in certain healthcare investment funds established pursuant to the Saudi Arabian Capital Market Authority's Investment Funds Regulations. Such investment funds have invested in sectors as diverse as pharmacies and clinics to small, mid-sized and large hospitals. In addition, our understanding is that the Ministry of Health has, to date, not objected to investors who meet the qualified foreign financial institutions requirements acquiring listed securities of entities operating in the healthcare sector.

For transactions in the UAE, parties should consider whether the relevant regulators will permit an entity incorporated in the Abu Dhabi Global Markets (ADGM) financial free zone to act as the holding company and, if yes, should use such entity to make their investment. In jurisdictions outside of the UAE, if GCC or non-local investment is permitted, investors should consider establishing their acquisition or joint venture vehicles in the ADGM so they can take advantage of the flexibility of the corporate forms with multiple classes of shares permitted, enforceable put and call options, and tag-along and drag-along rights as well as a clear process to register and enforce security. In addition, the ADGM has adopted English law as its governing law, giving greater certainty as to the meaning of and manner in which key transaction terms will be interpreted. Another benefit of establishing in the ADGM is that any entity incorporated in the UAE can take advantage of the UAE's extensive double-taxation treaty network (assuming, of course, that the entity meets certain substance requirements).



3. SIMILAR TO OWNERSHIP, LICENSING OF HEALTHCARE FACILITIES (INCLUDING HOSPITALS, CLINICS AND PHARMACIES) IS OFTEN TIMES LINKED TO THE NATIONALITY OF THE LICENSE HOLDER.

For most activities in the healthcare sector, investors will need to apply for and maintain a license from the relevant regulator. For example, in the UAE, most provider licenses issued by the Ministry of Health & Prevention, as well as relevant health authority licenses, require that the license holder is a UAE national. In Saudi Arabia, the Ministry of Health requires that the licensee for clinics, polyclinics, pharmacies, etc. is a Saudi national and that, subject to a number of narrow exceptions, the medical manager listed on the license is also a Saudi national. In addition, there is a general requirement that, subject to a number of exceptions, supervisors/management of healthcare institutions are Saudi nationals.

An investor seeking to acquire a healthcare facility in the GCC will typically be required to submit a request to the relevant ministry or authority requesting an initial approval or no-objection certificate for the transfer of the facility. Following the share or business transfer, the investor would submit a follow-on application to update the relevant license with their details as owner, though the medical manager or other individuals who may be listed in the license will not change.

Another point to note is that the relevant license may be restricted to a certain number of beds or specialisations for hospitals, polyclinics, etc. and, for pharmacies, may be restricted to a certain number of pharmacy branches depending on the form of entity. The requirements will vary from jurisdiction to jurisdiction. For example, in Saudi

Arabia, individuals have been permitted to own up to 30 pharmacies, while limited liability companies which are not wholly owned by pharmacists are capped at five. In the UAE, the license will be issued in the local's name, and such license holder is generally restricted to holding no more than two licenses (though there are some important practical exceptions to this limitation).

If there is any discrepancy between the number of facilities/beds listed on the target's license and the number permitted under the relevant regulation, investors should request that their counsel discuss the same with the relevant ministry or authority to determine whether specific exemptions apply.

4. HEALTHCARE FACILITIES MUST COMPLY WITH AN EVOLVING REGULATORY LANDSCAPE WHICH IS BECOMING MORE DETAILED AND COMPLEX.

Investors are often times surprised by the number of regulators involved with the licensing of a business operating in the healthcare sector. In addition, parties acquiring hospitals or clinics have found that such hospitals or clinics (particularly if more than 10 to 15 years old) sometimes have outstanding issues/reports with the local civil defence, municipality and/or health department and are operating on temporary licenses. Healthcare facilities which do not comply with the latest regulations could face costly and lengthy processes to bring their facilities into compliance.

Quite often such issues arise when facilities were constructed before purpose-built healthcare facilities were the norm. Those who have been in the region for significant periods of time will likely recall when most clinics/specialists did business out of converted villas and

other facilities which were not purpose-built to service the healthcare sector. It should come as no surprise that many older mid-sized or regional medical centres also started life as something other than a hospital and, over time, were slowly expanded. Often times such facilities will not fully comply with the latest rules issued by the relevant health regulator, civil defence or municipality relating to ingress/ egress, fire safety, ventilation, width of hallways, number and size of elevators, size of patient rooms, waiting rooms, sanitation, and waste disposal requirements for each medical facility.

For example, in Saudi Arabia, the Ministry of Health, the Central Board for Accreditation of Healthcare Institutions (CBAHI), the relevant municipalities and the civil defence each maintain standards by which a healthcare facility must abide. Each healthcare facility is subjected to a physical inspection in order to obtain its license from the Ministry. The Ministry of Health regulations also deal with the mix of departments and supporting services required for a facility to qualify as a hospital (and be open to foreign investment) rather than as a polyclinic or clinic. The CBAHI standards also relate to the condition of various medical equipment.

If an investor is considering a first-time acquisition in the regional healthcare sector, often times it is advisable to appoint an expert consultant to evaluate the condition of the target facility and to determine whether any expense to upgrade the facility will be needed in order to comply with regulatory requirements, so that such expenses/ requirements can be taken into consideration as the opportunity is assessed.

5. THE REGION HAS SEEN AN INCREASED INTEREST IN NEW MODELS OF HEALTHCARE PROVISION SUCH AS MANAGED CARE.

Managed care, where the insurer owns the healthcare provider or vice versa, has been quite successful in some jurisdictions outside the region (e.g. Kaiser Permanente in the United States). We are aware that a number of governments, healthcare providers and regulators have begun exploring the managed care model in order to reduce the overall cost of healthcare while enhancing population health. The rationale for the managed care model is that if the payor (i.e. the insurer) and the provider (i.e. the hospital or healthcare system) are aligned, they will work to achieve greater population health by introducing preventive measures at an earlier stage, thereby reducing long-term healthcare costs and, presumably, increasing profitability.

One of the main limitations to the managed care model is that many of the regional insurance laws/ regulations prevent insurance companies from owning providers and providers from owning insurance companies. For example, in the UAE, our understanding is that healthcare providers cannot own insurers and insurers cannot own providers. Such a restriction also applies to third-party administrators. That being said, it is not clear whether an insurer can be owned under a common holding structure with a healthcare provider.

For parties considering exploring managed care, the model typically takes one of two approaches: (i) a restrictive approach where members of the managed care organization are limited to visiting hospitals within the network for all care save for specialised care and (ii) a less restrictive approach where members have the option to go

If an investor is considering a first-time acquisition in the regional healthcare sector, often times it is advisable to appoint an expert consultant to evaluate the condition of the target facility.

out of network for certain elements of their care. The less restrictive approach typically results in higher premium to the patients.

As the regional healthcare market continues to develop, we expect that parties will explore the use of contractual arrangements to synthesize the managed care model. In addition, regional governments, which in many cases self-insure, have sought to encourage government-owned providers to participate more actively in the management of national patient populations in order to achieve many of the objectives of the managed care model (i.e. increased population health and reduced government cost).

6. A NUMBER OF LIMITATIONS CONTINUE TO APPLY TO CLINICAL TRIALS OF PHARMACEUTICAL PRODUCTS AND MEDICAL DEVICES.

In order to be legally entitled to conduct medical research, a healthcare provider typically must apply for and receive a research license (or similar) from the relevant health authority (e.g. DHA in Dubai or HAAD in Abu Dhabi). After receipt of the license, the researcher faces a number of hurdles, some of which are quite difficult to surmount, before they can commence clinical trials.

By way of example, in the UAE if a healthcare facility has the requisite research license, properly qualified research practitioners are generally able to put forward proposals for research provided that the research is approved by an internal ethics committee and does not contravene (i) any law of the UAE or the relevant Emirate; (ii) international ethical principles; or (iii) any policy or publication of the Emirate's health regulator including the HAAD's "Standard Operating Procedure for Research Ethics Committees" and the DHA's Code of Ethics and Professional Conduct.

The researcher must also consider whether the research will be conducted utilising unregistered medicines, pharmaceuticals or medical devices. If such will be utilised, the researcher will need to apply for and receive permission to import the relevant pharmaceuticals or medical devices into the UAE. Our understanding is that researchers have faced significant issues receiving such permissions. While



the relevant legislation does contain some exemptions permitting parties to import unregistered medicines in certain circumstances, including in response to requests made by hospitals affiliated with the health authority in an Emirate, medical research is not explicitly included as a justification for importation. Accordingly, clinical trials which involve drugs which have not yet been approved for use in the UAE (so-called investigational new drugs) typically cannot be conducted in the UAE.

Similar restrictions apply to clinical trials in many jurisdictions in the region, with some exceptions.

THE PATH AHEAD

As regional healthcare M&A and privatization activity continue to strengthen and develop, investors should ensure that they have a clear plan and retain experienced advisors who can provide guidance on how to structure the entity and implement and navigate the various restrictions and regulations in order to complete their



transactions in a timely manner. In addition, governmental authorities seeking to privatize their healthcare assets should have a clear game plan on how they will achieve such privatization while ensuring population health and, hopefully, a reduction on spend per patient. From the perspective of economic diversification, to the extent that healthcare provision continues to be a strategic focus, governments should consider how they can reduce overall regulation to permit research on new drugs and devices and investment in new approaches to provision such as telemedicine and app-based tools, so that the region continues its development into a global leader in the healthcare sector.

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About our Middle East practice

King & Spalding has been advising clients in the wider Middle East region for more than 30 years and is recognized for its expertise in Islamic finance, corporate finance, debt capital markets, infrastructure projects, energy, international arbitration, real estate and construction, international trade, mergers and acquisitions, and private equity. Our Dubai, Abu Dhabi and Riyadh offices are home to a team of internationally qualified lawyers who are consistently recognized by independent directories for being market leaders in their fields of expertise. Our clients in the Middle East include some of the most high-profile oil and gas, energy, and power companies, banks and finance houses, and significant investors and multinationals. Our team has won numerous awards for our ground-breaking deals. In reference to King & Spalding, Chambers Global mentions that the firm “remains a heavy hitter in the region, as evidenced by the quality of its lawyers and deals”.

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