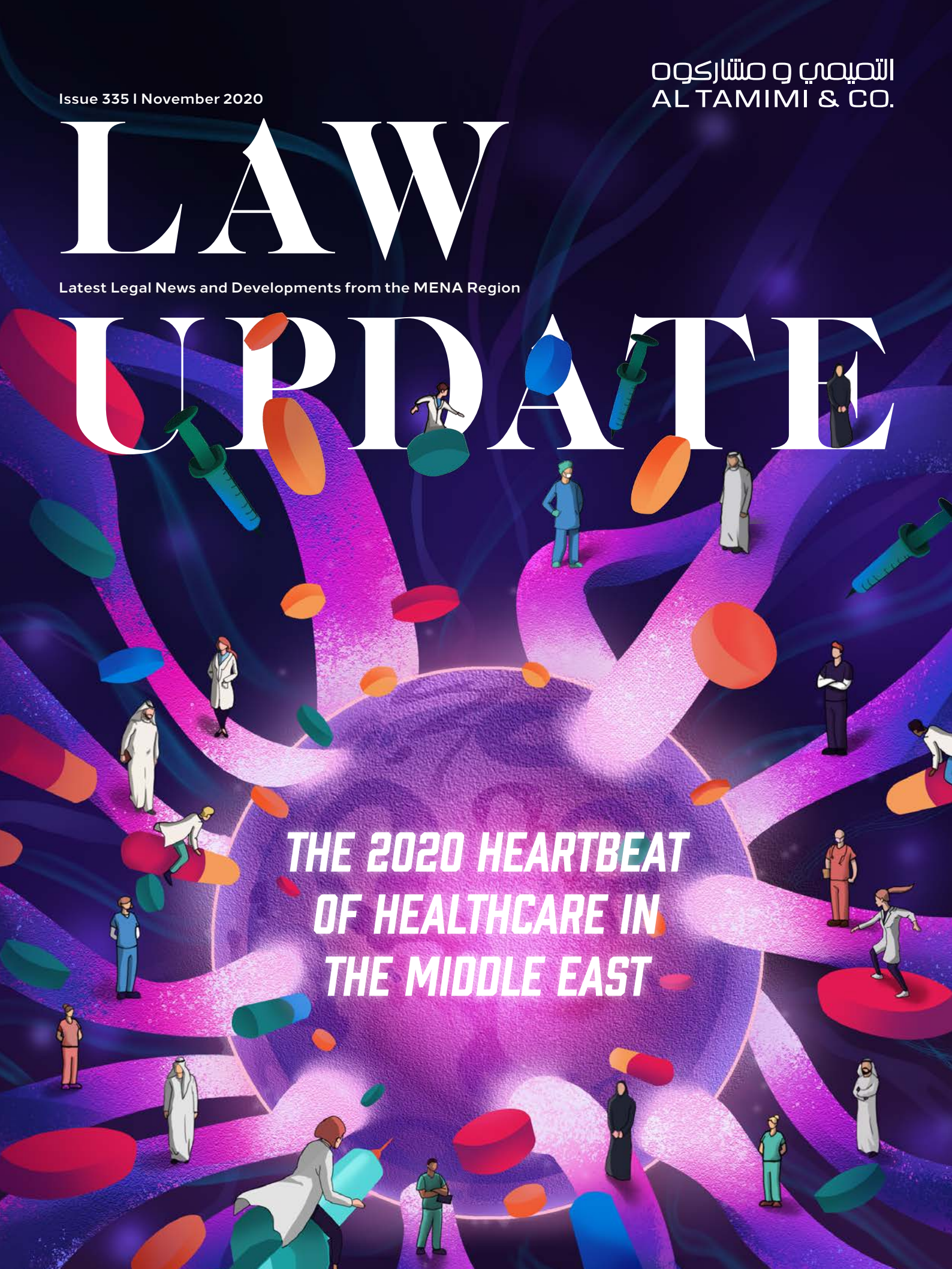
Issue 335 I November 2020

التميمي و مشاركوه
AL TAMIMI & CO.

LAW UPDATE

Latest Legal News and Developments from the MENA Region



THE 2020 HEARTBEAT OF HEALTHCARE IN THE MIDDLE EAST

BUSINESS DEVELOPMENT & MARKETING DIRECTOR
Barbara Koenen-Geerdink
b.koenen@tamimi.com

LEGAL EDITORIAL COMMITTEE CHAIR
Mark Brown
m.brown@tamimi.com

PUBLICATION AND CREATIVE LEAD
Shriya Sanjeev
s.sanjeev@tamimi.com

LEGAL EDITOR
Siobhan Farrell
s.farrell@tamimi.com

FOCUS ARTWORK
Saif Zulfiqar
saifzk.01@gmail.com

FEDERAL GAZETTES
Zane Anani
z.anani@tamimi.com

TRANSLATION
Vincent Percival
v.percival@tamimi.com

For more information on Law Update
info@tamimi.com

www.tamimi.com

ISSUE #335

IN THIS ISSUE

SAMER QUDAH
Managing Partner
s.qudah@tamimi.com

Welcome to November's Law Update.

As we move towards the end of what has been a particularly challenging year, it is befitting that the main focus of this edition is healthcare. Thankfully, it seems the world has turned a corner with a number of vaccines on the horizon; however, COVID-19 is not the only topic our Healthcare Practice Group explores as they explain and analyse an array of healthcare industry related legal and regulatory developments across the MENA region, as detailed by Andrea Tithecott and Christina Sochacki.

On the Kuwaiti legal side, a number of key developments are examined commencing with the rapid evolution of the country's legal system, which, over the past decade, has witnessed positive developments that offer companies and investors (internationally and regionally) certainty and comfort when doing business in Kuwait. The newly approved bankruptcy law, designed to increase protection for troubled businesses as well as provide options to avoid bankruptcy before being forced by the law to declare bankruptcy, is analysed by our Kuwaiti experts who highlight the importance of this law in modernising the country's legal system. Remaining with the financial sector, our Banking team highlights considerations to be taken into account by creditors when accepting guarantees, which includes warnings of potential pitfalls to avoid.

Our General articles cover a variety of matters, including the new Data Protection Law introduced by the Dubai International Financial Centre, which our lawyers discuss as being critical to protecting confidential, sensitive, and personal information. Mindful of the uncertainty of the current COVID-19 climate, our Private Client Services team recommends the importance of reviewing and ensuring careful estate and succession planning in the UAE. Another practical implication of the pandemic to be considered is the way in which annual leave has been used and how excess leave, accruals, and carry -overs should be addressed in the UAE. On a lighter note, our TMT practice group considers the lucrative nature of the world of video gaming and the opportunities it provides to clients to potentially diversify their business in this fast changing technological world.

As the trading partnership between the Middle East and East Africa continues to blossom, encouraging developments in the arbitration arena are being reported, with East African countries seeking to align their paths of legal recourse with those of international treaties..

Moving to Qatar, we provide an introduction to the funds' regime in the Qatar Financial Centre, highlighting the types of funds that may be established as well as discussing the differences between such types of funds.

Last month, a key development to a longstanding staple instrument of business transactions in the United Arab Emirates, the cheque, was introduced via the new Commercial Transactions Law. The new law proposes to relax the penalties relating to bounced cheques, whilst offering new forms of protection for credit-based commercial transactions.

I hope you enjoy this edition. Should you have any queries or comments, please do not hesitate to reach out.

CONTENTS

Judgments

General

Jurisdiction Update

The 2020 Heartbeat of Healthcare in the Middle East

Jurisdiction Feature: Kuwait

First-of-a-kind Dubai Court of Cassation judgment: a lawyer's right to comment on court rulings

Law Update Judgments aim to highlight recent significant judgments issued by the local courts in the Middle East & North Africa. Our lawyers translate, summarise and comment on these judgments to provide our readers with an insightful overview of decisions which are contributing to developments in the law. If you have any queries relating to the Law Update Judgments please contact info@tamimi.com.

Mosaab Aly
Senior Associate
Litigation
m.aly@tamimi.com

Zane Anani
Senior PSL
Knowledge Management
z.anani@tamimi.com

Introduction

In a recent and first-of-a-kind Dubai Court of Cassation judgment dated 2 July 2020, the court established that a lawyer has the right to comment on court rulings and provide insight into a court's interpretation of legal rules as that commentary is considered constitutionally protected speech under UAE law. This case considers how a lawyer can express their opinion on a judgment in a journal. As part of a lawyer's practice, a lawyer is expected to analyse and comment on case law. This may involve disagreeing with the rationale of a court's decision. In this Dubai Court of Cassation judgment, the Claimants had filed proceedings against the defendant law firm after it published an article in a journal commenting on a court judgment in which one of the claimants was a party. The Claimants filed a claim requesting material and moral damages of over AED 100 million (US$27 million) for alleged unauthorised disclosure of certain details by the Defendant.

In its judgment, the Court of Cassation established the meaning of protected speech, the scope of public interest privilege and the conditions that are applied to invoke this privilege.

The facts of the case

The Claimants filed a claim against the Defendant for allegedly publishing commentary on a court decision, in bad faith, that included unauthorised disclosure of certain details. The Claimants argued that the

Defendant did this deliberately , and that the Defendant should have taken more care when publishing the article.

The Claimants also argued that the article commenting on the judgment was published contemporaneously with the Claimants' announcement of a major project, which the Claimants said affected its dealings with potential clients. The Claimants further maintained that the interests the Defendant aimed to achieve were of little significance, unlawful, and disproportionate to the alleged harm the Claimants suffered. According to the Claimants, this demonstrated that the article was published in bad faith with the deliberate purpose of causing harm and therefore, as alleged, was an abusive exercise of rights.

The court considered the case in light of constitutional provisions relating to freedom of speech and other forms of expression.

Court's findings

The Dubai Court of Cassation held that it was the intention of the legislator in the UAE to protect freedom of opinion and expression in word, deed, and other modes of expression under the basic principles of the Constitution.

In its decision, the Cassation Court held that any commentary on court decisions will be of interest to specialists in the legal field. Indeed, the Court of Cassation decided that commentaries contribute to the development of current law and provide insight into how the laws in force should be interpreted...

However, according to the Court of Cassation judgment, there are conditions that must be applied when publishing commentary on a court ruling, as follows:

1. The Commentary should only concern a judgment for which all means of review have been exhausted so as to avoid suspicion of an exertion of influence on any decision on appeal;
2. The commentary should discuss the ruling's underlying principles but not discuss the panel that issued the ruling or the parties involved;
3. The commentary should be drafted by a specialist legal practitioner, and should appear in a lawful, specialised publication, in hard copy or electronic format; and
4. The commentary must accurately report, analyse, and contextualise the ruling in order to ascertain its meaning and potential implications. The commentator should then assess the ruling and draft a legal opinion outlining the facts, the reasoning of the final judicial decision and the extent of its conformity with the law, logic, and scientific and legal doctrines prevailing in society.

Lawful exercise of a right

It is further established that Articles 104 and 106 of the Civil Transactions Law embody the principle that no liability shall arise in respect of damages resulting from the lawful exercise of one's rights, including the right to comment on court rulings for which all means of review have been exhausted.

The legislation describes four instances of abuse and the unlawful exercise of a right:

1. exercising a right with the sole intention of harming another. Intent may be inferred from knowingly exercising a right without legitimate interest to the detriment of another;
2. where the right being exercised is directed to achieve an unlawful purpose that is contrary to the rules of Islamic Sharia, the law, public policy or morality;
3. here the interest to exercise the right is of little significance and disproportionate to the harm that is caused to others; and
4. where the right being exercised exceeds the normal bounds of inconvenience. The burden of proof lies with the aggrieved party. It is not sufficient that the aggrieved party prove that the holder of the right perceived that harm was likely to occur by exercising his/her right as this does not in and of itself constitute a wrongful motive.

The Cassation Court held that any commentary on court decisions will be of interest to specialists in the legal field. Commentaries contribute to the development of current law and provide insight into how legal rules in force should be interpreted.

It is settled, in line with the holdings of the Court of Cassation, that inferring and evaluating the existence, or otherwise, of an abuse of rights, intent to attack, vex, and/or harm another, interests which are of little significance and disproportionate to the harm caused to another, or an exercise of such rights beyond the normal bounds of inconveniences, are questions of fact for the trial court. The trial court must assess, within its discretion, find facts and weigh the evidence, presumptions, and documents presented in the case, provided it demonstrates an understanding of the legal issues of the case and provides sound reasoning, based on evidence, which is sufficient to sustain its decision and leads to the conclusions reached.

Legitimate right to publish and comment on judgments

In light of the above legal principles, the Court of Cassation ruled that it is clear that the article's wording complies with the regulations governing the right to comment on court rulings, based on justified grounds. The court also found that the article does not attack the panel that issued the ruling or the parties to the dispute. As such, it was held that the Claimants did not provide proof that the commentator's sole intention was to cause prejudice and/or harm.

The Court of First Instance and the Court of Appeal had previously adopted this reasoning and dismissed the Claimants' case. The Court of Cassation adopted and reiterated the reasons given by the Court of First Instance that the Defendant is an UAE-licensed firm of advocates and legal consultants with a website where they publish recent court rulings and legal principles for the purpose of disseminating legal knowledge, as evidenced by the article cited by the Claimants. The Defendant publishes court rulings in order to highlight important rulings of the local courts.

The Court also concluded that the Defendant's staff were not at fault, having exercised their legitimate right to publish and comment on news in relation to the facts before the courts, the judicial proceedings, and the rulings rendered by the Court of Cassation via a brief synopsis of the contents of the ruling which was not under a publication restriction by order of the Court. The decision being commented on was not a secret of private life deserving of protection for it was already in the public domain and freely accessible to an unlimited number of people. There was nothing on record as far as evidence or documents proving that the Defendant was at fault. The Claimants could not substantiate any of its allegations. The Court of Cassation therefore found that one of the elements in this tort cause of action was not met with respect to the Defendant, and the action lacked proper factual support and legal basis. As a result, the Claimants' case was dismissed.

Conclusion

The Court of Cassation found that the law firm, in this case, exercised a lawful right to comment on final court rulings, and that the right of legal practitioners to publish commentaries on court rulings is a protected constitutional legal right provided that the publication has to comply with certain conditions that the court has indicated.

The Court of Cassation also considered the importance of legal commentary to enable legal practitioners to learn and gain insight in developing areas of law. It is well established that commentaries contribute to the development of current law and provide insight into how the legal rules in force should be interpreted. The test applied by the courts for determining whether the legal commentary is protected speech also provides lawyers guidance on what they can publish.

For further information, please contact Mosaab Aly (m.aly@tamimi.com).

Who is liable to pay VAT?

A closer look at the Egyptian VAT Law

Law Update Judgments aim to highlight recent significant judgments issued by the local courts in the Middle East & North Africa. Our lawyers translate, summarise and comment on these judgments to provide our readers with an insightful overview of decisions which are contributing to developments in the law. If you have any queries relating to the Law Update Judgments please contact info@tamimi.com.

Muhammad El Haggan
Associate
Litigation
m.elhaggan@tamimi.com

Janet Gooi
Associate
Tax
j.gooi@tamimi.com

Taxes are a source of revenue for the government which contribute to economic growth and infrastructure. Whilst there are several types of taxes, they can generally be classified as direct or indirect taxes. Direct taxes are levied on the income or profits of an individual or organisation and cannot be transferred to another person. Examples of direct taxes include income or corporate tax, property transfer tax, and capital gains tax.

On the other hand, with respect to indirect taxes businesses act as tax collectors and the burden of indirect taxes are ultimately borne by the final consumer or end user. Indirect taxes include sales tax, value-added tax ('VAT'), excise tax (also known as "sin tax" levied on specific goods which are harmful to human health or the environment).

However, the question arises as to the transferability of indirect taxes; whether the burden of indirect tax be transferred to the supplier in a scenario where both the consumer or end user and supplier contractually agree to do so.

In Egypt, by way of a judgment issued in 2010 for Petition No. 1315/75JY, the Court of Cassation established the principle in 'shifting' the indirect tax burden. In this article we examine the facts and the implications arising from the judgment.

Claim: who is liable to pay the general sales tax?

In this case, an employer filed a petition for the annulment of a judgment issued by the Court of Appeal ordering the employer to pay the sales taxes related to a construction contract notwithstanding its agreement with the contractor (i.e. the service provider) to shift the burden of tax and the contract price which included the tax due. According to the petitioner, the appealed judgment disregarded the agreement of the parties where the payment of all fees and taxes would be borne by the contractor, which inherently included sales tax.

Court of Cassation judgment: upholding parties' agreement

The Court of Cassation deduced from the relevant sales tax legislation that the employer ('Petitioner'), being the consumer, is the party who is legally required to pay the sales tax to the contractor for the provision of services by the contractor, who will subsequently remit the tax to the tax authority. The Court of Cassation concluded that sales tax is a type of indirect tax which is ultimately the responsibility of the consumer while the service provider is the party legally required to collect and remit the tax to the tax authority. However, the Court of Cassation went on to say that

> *"parties to a contract may agree to shift the payment burden to the service provider".*

Therefore, given that the parties contractually agreed that the tax should be borne by the contractor, the Court of Cassation held that the appealed judgment contradicted the agreement of the parties, and accordingly ruled to annul the Court of Appeal's judgment.

Observations

While sales tax is no longer applicable in Egypt in accordance with the Value-Added Taxes Law (Law No. 67 of 2016) ('VAT Law'), it is arguable that the principle established by the Court of Cassation in connection with shifting the burden of tax under the sales tax regime should be applicable to the VAT regime. Both sales tax and VAT legislation[1] generally reflect international indirect tax principles and identify that: (i) the supplier or provider of goods and services is liable to collect and pay the tax to the tax authority; (ii) tax falls due when the goods are sold or service is provided; and (iii) the tax value shall be added to the price of the service.

It is notable that these were the provisions in the Sales Tax Law upon which the Court of Cassation relied in reaching this conclusion the reasons for which are substantively identical to the VAT Law. Further, notwithstanding that the consumer or recipient generally bears the burden of tax under the sales tax regime, it is worth noting that the Court of Cassation respects the terms of commercial contracts where parties contractually agree to shift the payment burden to the service provider.

Thus, to the extent parties contractually agree to pass the VAT burden to the service provider, this principle established by the Court of Cassation should be applicable and could, in the future, hypothetically be used to shift the VAT burden.

For further information, please contact Muhammad El Haggan (m.elhaggan@tamimi.com) or Janet Gooi (j.gooi@tamimi.com).

[1] *Article 1 of the VAT Law provides that the taxpayer is the person required to collect and pay taxes to the tax authority, whether he is a producer, merchant or service provider. Article 2 provides that tax is due on commodities and services unless exempt explicitly by law. Article 5 provides that the tax falls due when the commodity is sold or a service is provided by the taxpayer. Article 11 provides that the value-added tax shall be added to the price of commodity or service sold by the taxpayer.*

Corporate
Structuring / Tax

UAE new approach to economic substance regime

Izabella Szadkowska
Partner
Corporate Structuring
i.szadkowska@tamimi.com

Shiraz Khan
Head of Taxation
s.khan@tamimi.com

Due to the light taxation regime, the UAE has been a preferred choice for many businesses as a jurisdiction in which to firm their operations. The UAE is a member of the Organisation for Economic Co-operation and Development ('OECD') and as such, it is subject to the Base Erosion and Profit Shifting ('BEPS') regime.

The BEPS particularly looks after globally adopted measures to tackle tax avoidance, improvement of the coherence of international tax rules and ensures a more transparent tax environment.

As part of the UAE's commitment as a member of the OECD Inclusive Framework, and in response to an assessment of the UAE's tax framework by the European Union Code of Conduct Group on Business Taxation, the UAE introduced the Economic Substance Regulations ('ESR'), on 30 April 2019 under Cabinet of Ministers Resolution No 31 of 2019 and Guidance to the application of the ESR.

Recently, the UAE Cabinet of Ministers made certain amendments to the ESR to ensure regular recording and reporting of all the economic activities undertaken by UAE entities, including companies, branches and representative offices.

On 10 August 2020, the UAE Cabinet of Ministers issued Resolution No. 57 of 2020 ('New Regulation') where it addressed those changes. The New Regulation replaced the original legislation, in particular the Cabinet of Ministers Resolution No. 31 of 2019.

The New Regulation has a retrospective application to licensees, from financial years starting on or after 1 January 2019.

Subsequently, on 19 August 2020, the Ministry of Finance ('Ministry') issued the revised guidelines, under Ministerial Decision No. 100 of 2020 ('New Guidelines').

Finally, the Ministry, on their website, made available a helpful set of sample questions with answers concerning the economic substance regime.

In this article, we will highlight some of the more prominent provisions introduced under the New Regulation and the New Guidelines.

What is new?

The key developments under the economic substance regime introduced under the New Regulation and New Guidelines are as follows:

1. Definition of licensee: The regime only applies to: (i) juridical persons (persons with separate legal personality); and (ii) unincorporated partnerships registered in the UAE, each of which shall conduct a "relevant activity" in the UAE.

Therefore, natural persons, sole proprietors, trusts and foundations no longer fall within the scope of the regime.

2. Introduction of "Exempted Licensee" category: The New Regulation introduced a new category of licensees, i.e. "Exempted Licensees". The Exempted Licensees are not required to meet the economic substance test or submit the economic substance report. However, they are required to submit the economic substance notification along with the documents/information evidencing the fact that they are exempt from the application of the economic substance regime.

The Exempted Licensee category includes an entity that is:

- an investment fund;
- a tax resident outside the UAE;
- wholly owned by UAE residents and (i) is not part of a multinational group; and (ii) only carries out business in the UAE; and
- a licensee that is a branch of a foreign entity, whose relevant income is subject to tax in a jurisdiction other than the UAE.

Entities directly or indirectly owned at least 51 per cent by the UAE government are no longer specifically exempted from the application of the regime.

3. Branches status: The New Guidelines confirm that branches do not have a separate legal personality from their "parent" or a "head office". The "head office"/"parent" entity of the branch registered in the UAE must report any relevant activities of its branches in a single consolidated notification and submit a single economic substance report that also addresses its branches.

The Ministry clarified that a UAE branch of a foreign entity that carries out a relevant activity would be required to comply with the New Regulation as if it were a separate legal person, unless the relevant income of the branch is subject to tax in the jurisdiction of the foreign head office/ parent entity. Where a UAE entity carries on a relevant activity through a branch registered outside the UAE, the UAE entity is not required to consolidate the activities and income of the foreign branch for purposes of the New Regulation, provided the relevant income of the foreign branch is subject to tax in the foreign jurisdiction where the branch is located.

4. Scope of "distribution and service centre business" activity: Under the New Regulation, we find an amended definition of "distribution and service centre business". Specifically:

- there is no longer a requirement for the goods to be imported and stored in the UAE for an entity to be considered a "distribution and service centre business"; and
- there is no longer a requirement for the services to be provided in connection with a business outside the UAE. As a result, the provision of a service by the licensee to a foreign related party would be considered a "distribution and service centre business".

On 10 August 2020, the UAE Cabinet of Ministers issued Resolution No. 57 of 2020 ('New Regulation') where it addressed those changes. The New Regulation replaced the original legislation, in particular the Cabinet of Ministers Resolution No. 31 of 2019.
As far as the immediate future is concerned, it is critical for businesses in the UAE to commence preparations immediately, re-assess their UAE position under the New Regulation and consider whether any restructuring of its business operations should be undertaken to satisfy the economic substance test, to avoid potentially substantial sanctions being imposed.

5. Scope of "high risk intellectual property" licensee: Under the revised regime, the definition of a high-risk intellectual property licensee has been limited to an intellectual property business which:

- did not create the intellectual property asset;
- acquired the intellectual property asset from either: (i) a connected person; or (ii) in consideration for funding research and development by another person situated in a foreign jurisdiction; and
- licenses or has sold the intellectual property asset to a connected person or earns separately identifiable income from a foreign connected person in respect of the use or exploitation of the intellectual property asset.

6. "connected person" and "group": The amended definition of a "connected person" has been introduced. It provides, entity A is a "connected person" to entity B if the two entities form part of the same group. A "group" has been defined as two or more entities related through ownership or control such that they are required to prepare consolidated financial statements for financial reporting purposes under the applicable accounting standards.

7. Re-submission of Notification: Licensees that have already submitted the economic substance notification directly to their regulatory authorities, are required to re-submit a notification under the Ministry's portal once available.

8. Economic Substance Report: The licensees are now required to provide financial reports as part of the economic substance report submission.

9. Penalties for non-compliance: An administrative penalty of AED 20,000 (US$ 5,500) is now imposed on a licensee or exempted licensee who fails to submit the economic substance notification. Previously, the penalty for failure to notify ranged between AED 10,000 (US$ 2,750) and AED 50,000 (US$ 13,650). A licensee or exempted licensee who fails to submit the economic substance report or satisfy the economic substance test for each financial year will be subject to an administrative penalty of AED 50,000 (US$ 13,650). Where the licensee or exempted licensee repeatedly fails to meet the economic substance test or submit the economic substance report, the penalty has been increased from AED 300,000 (US$ 81,700) to AED 400,000 (US$ 108,900) and the licence of the licensee or exempted licensee may be suspended, revoked or refused renewal by the regulatory authority.

10. Introduction of National Assessing Authority:
The Federal Tax Authority has become the "National Assessing Authority" to oversee the compliance and control with the New Regulations. The role of the specific free zone/ onshore regulatory authorities will be limited to the collection of information from licensees and reporting of such information to the National Assessing Authority.

What does the future hold?

As the immediate steps we encourage each licensee (including the exempted licensee) to submit:

- the notification electronically on the Ministry portal within six months from the end of their financial year.
- the economic substance report within twelve months following the end of their financial year end (i.e. by 31 December 2020 for the financial year ended 31 December 2019).

The regime is still new to the overall UAE legal framework. Businesses, their advisors as well as authorities are yet to understand the various aspects of this regime and how to best approach the requirements in practice. As with many legislative novelties, most would agree that the key will be to achieve a balance between encouraging businesses to comply, but at the same time, adopting a sufficiently flexible approach that can fit the variety of business models that function in today's business world.

As far as the immediate future is concerned, it is critical for businesses in the UAE to commence preparations immediately, re-assess their UAE position under the New Regulation and consider whether any restructuring of its business operations should be undertaken to satisfy the economic substance test, to avoid potentially substantial sanctions being imposed.

For further information, please contact Izabella Szadkowska (i.szadkowska@tamimi.com) or Shiraz Khan (s.khan@tamimi.com).

Managing annual leave in the COVID-19 era: UAE employment law considerations

Mandeep Kalsi
Senior Associate
Employment & Incentives

As the effects and impact of the pandemic continue to unravel, the issue of unused leave and the rules on carry-over are likely to become a pressing agenda item for many businesses and HR managers across the UAE.

Introduction

Employees working across various sectors in the UAE have historically utilised much or all of their annual leave during the scorching summer months or whilst the academic term paused for the much anticipated school holidays. However, in 2020, standard practice on annual leave has been upended by the COVID-19 pandemic. When normal business operations were provisionally suspended (due to various UAE Government mandated lockdown and/or curfew measures), some employers required employees to utilise their annual leave (either in whole or in part). Others were able to continue working remotely or were deemed key or critical personnel, thereby inhibiting their ability to utilise their accrued untaken leave balances. As we approach the end of 2020, many companies are (or will be) struggling with their annual leave policies as a result of COVID-19 . According to the "COVID-19 Middle East Survey" from global insurance brokerage firm Willis Towers Watson, almost two-fifths of the UAE employers surveyed intended to allow staff to carry forward unused leave days as a result of COVID-19 into 2021. However, 36 per cent surveyed were unsure how to handle the excess leave days and 22 per cent said any unused days would be forfeited.

This article briefly explores the leave framework in the UAE and some recommended solutions for employers to effectively and appropriately manage annual leave in the COVID-19 era.

Legal framework

The dilemma for most employers is ensuring that their employees do not accumulate high leave balances at year-end (or at termination) as this will invariably create an ongoing liability on their balance sheets. From a planning perspective, employers will want employees to take leave progressively in order to avoid employees building up significant leave balances and then wanting to take extended holidays as this will prove disruptive to business continuity. But what does the law in the UAE say?

The UAE's employment law regime operates under a dual legislative framework: for those employees working in the Dubai International Financial Centre ('DIFC') or Abu Dhabi Global Marketplace ('ADGM') free zones, the DIFC Law No. 2 of 2019 as amended (the 'DIFC Employment Law') and ADGM Employment Regulations 2019 as amended (the 'ADGM Employment Regulations'), apply wholesale. For all other employees working in the UAE's private sector (including the other UAE free zones), they are subject to the scope and remit of Federal Law No. 8 of 1980 as amended (the 'UAE Labour Law'). Each employment regime offers differing provisions regarding annual leave utilisation and carry-over obligations and requirements.

DIFC Employment Law and ADGM Employment Regulations

In the DIFC, points to note regarding the minimum framework on annual leave include:

- employees are entitled to a minimum of 20 working days' paid annual leave (after 90 days of employment);
- employees are entitled to carry forward up to five working days of accrued but untaken annual leave into the next annual leave year for a maximum period of 12 months, after which any unused annual leave automatically expires;
- unless otherwise agreed in writing by the employee (and/or on termination of the employment), an employee cannot receive a payment in lieu of annual leave; and
- employers may require an employee to take annual leave on specified days in the current annual leave year by giving at least seven days' prior written notice to the employee.

In the ADGM, the same framework as in the DIFC is adopted and applied in the ADGM Employment Regulations.

UAE Labour Law

Comparably, the UAE Labour Law provides for an altogether different regime:

- after the first year of service, employees are entitled to 30 calendar days of paid leave per annum (approximately 22 working days);
- employers have the right to dictate when leave should be taken in any given holiday year;
- the concept of "use it or lose it" is not expressly provided for – where leave is unutilised by holiday year-end, employees have the right for such accruals to either be encashed (before the next holiday year) or carried forward to the next holiday year; and

- there is no cap on the number of days of carried-over leave; however, on termination, the Labour Court has historically permitted an employee to claim for accrued untaken leave for the two years preceding their termination only.

Options and recommendations for employers

From a practical planning perspective, employers will need to manage excess leave carefully to ensure that they are appropriately balancing statutory obligations against the need to maintain sufficient employee coverage and business continuity through to year-end:

- **Annual leave policy:** employers should communicate the terms of their annual leave policy and reach a considered consensus on carry-over provisions (statutory or otherwise) with respect to those employees holding high leave balances. The key is putting into place appropriate systems to ensure that between now and the end of the relevant leave year period, employees utilise their leave or where unable to carry forward arrangements are agreed.
- **Communication:** employers should engage in open and transparent dialogue with employees and make clear that employees must utilise any untaken annual leave within this limited window of time and ensure that prior approval is granted before any bookings are made. It will be fundamental for employers to maintain appropriate business continuity which will not be possible if employees are on leave concurrently. It is possible for employers to dictate when leave can be taken and any such arrangements should, so far as possible, suit both the business and the employees.
- **Follow-up/reminders:** most employers will have an online system through which leave can be ascertained and tracked. Employees should be periodically reminded where they still have annual leave remaining (or in excess of carry-over arrangements) periodically and in advance of year-end. Finally, employers should encourage employees to utilise their leave not just from a business perspective but from a general health and safety perspective.

Conclusion

The employment regimes in the UAE, DIFC and ADGM contain various provisions governing and regulating annual leave and it is important that employers take steps now to appropriately manage any excess leave accruals and carry-over issues. Measures introduced by the UAE Government to date have focused primarily on various employment-specific cost-cutting measures including the implementation of forced leave initiatives at times determined by the employer. However, as the effects and impact of the pandemic continue to unravel, the issue of unused leave and the rules on carry-over are likely to become a pressing agenda item for many businesses and HR managers across the UAE.

For further information, please contact Samir Kantaria (s.kantaria@tamimi.com) or Gordon Barr (g.barr@tamimi.com).

International Litigation Group / Technology, Media & Telecommunications

DIFC and ADGM data protection and commercial litigation: data protection in disclosure

Martin Hayward
Head of Technology, Media & Telecommunications
m.hayward@tamimi.com

Peter Smith
Senior Associate
International Litigation Group
p.smith@tamimi.com

In the November 2019 edition of Law Update, we explained the uses of data subject access requests ('DSARs') as tools in commercial litigation in the courts of the Dubai International Financial Centre ('DIFC') and the Abu Dhabi Global Market ('ADGM').

Since that article was published, the DIFC has introduced a new Data Protection Law (Law No.5 of 2020; the 'New Data Protection Law'). The New Data Protection Law substantially updated the DIFC's previous Data Protection Law (Law No.1 of 2007 as amended; 'Previous Data Protection Law'), setting out a new regime for governing data protection in the jurisdiction of the DIFC and the powers of the DIFC's Commissioner for Data Protection ('CDP').

In this second article in our series on the UAE's current data protection regimes as they apply in the UAE's common law jurisdictions, we look at considerations relating to data protection in the dispute resolution process and in the context of disclosure.

The disclosure or the 'discovery' of documents is a key part of any dispute resolution process. The DIFC and ADGM Courts have a default model of disclosure based on international arbitration norms, whereby in summary the parties: (a) provide documents in support of their claim or defence in a first phase known as 'standard' disclosure, upon which they will rely at trial; (b) make requests of their opponent for documents that are relevant and material to the outcome of the case (usually tabulated so that categories of documents relate to certain issues in the case); (c) respond to their opponent's requests and

reply to their opponent's responses to their own requests; and (d) search for and provide copies of documents falling within categories of disclosure as ordered by the judge or the tribunal.

Parties engaging in disclosure must do so in ways which comply with the relevant and applicable data protection laws. From the outset of a dispute, documents will be exchanged between parties, in pre-action correspondence and then in the formal disclosure process described above. Indeed, the early exchange of some documents may solve a dispute before a formal dispute resolution process is engaged.

In many cases, the momentum of the dispute resolution will be in the claimant's favour, as the court or tribunal will presume (whether explicitly or not) that the claimant should have the opportunity to extract information from the defendant to investigate and/or prove its case. This is particularly true in the case of fraud, where the claimant may seek early disclosure through a pre-action disclosure process against the likely defendant or a third party, or even by way of disclosure ordered through an injunction.

Parties subject to disclosure obligations must ensure that their disclosure of personal data and particularly data falling within "special categories of personal data" (such as health data or data relating to religious beliefs, for example) is disclosed in a lawful manner. What does this mean? The disclosure of personal data to a third party is a form of processing of personal data that is captured by all data protection laws, and certainly by the New Data Protection Law in the DIFC and the 2015 Data Protection Regulations in the ADGM ('ADGM Regulations'). So disclosure of personal data in a dispute resolution process is caught and regulated by data protection laws.

Under the New Data Protection Law, the processing of special categories of personal data is unlawful unless it is done in accordance with the general principles of personal data processing (Article 9), on a lawful basis under Article 10, and because a special reason under Article 11 applies. Article 11(f) expressly permits processing "necessary for the establishment, exercise or defence of legal claims (including, without limitation, arbitration and other structured and commonly recognised alternative dispute resolution procedures, such as mediation) or is performed by the [DIFC] Court acting in its judicial capacity".

A similar provision exists at Article 3(1)(e) to the ADGM Regulations, which refers only to processing "necessary for the establishment, exercise or defence of legal claims".The New Data Protection Law begs a question: what is a "structured and commonly recognised" form of ADR? Some dispute resolution processes would manifestly fall within this definition, such as DIFC Courts litigation in the Court of First Instance, Court of Appeal or Small Claim Tribunal, as would arbitration under the DIAC or DIFC-LCIA Rules, for instance. But is an ad hoc negotiation a "structured and commonly recognised" process?

Unsurprisingly, the parameters of this exception have not been tested. But this puts parties in a quandary. On the one hand, they may wish to adopt a 'cards on the table' approach from the outset, disclosing documents as soon as possible in a bid to early dispute resolution. The DIFC Courts' Rules have no formal pre-action process (unlike the English Civil Procedure Rules), and this too raises the question of whether the exchange of documents (constituting the processing of special categories of personal data) falls under the protection of Article 11(f) when the parties make such disclosure with the intention or expectation that a party will engage in a structured and common recognised form of dispute resolution but has not yet done so.

There are a number of steps parties can take if they are unsure of the lawfulness of their disclosure from a data protection law compliance perspective.

Firstly, parties may seek specific consent from people whose personal data will be disclosed. This may be appropriate and practical under certain limited circumstances. For instance, an employer may write to a former employee to seek consent for the limited disclosure of information in a dispute between the employer and a third party. However, the person whose consent is solicited may refuse to give it, and there will be logistical difficulties over the time taken and costs incurred to obtain consent, along with the potential that the consent may be withdrawn at some stage.

Secondly, redaction. Parties can redact personal data from documents by either taking a black marker to documents and neatly scoring out information, or (far preferably) using software to the same effect on screen. Some parties in disputes take this approach more fastidiously than others, e.g. by redacting all personal data relating to people not related to the dispute, for example where a bank is in a dispute with a client and the bank has processed the claimant's information in the same database as it has for third party clients. Agreement to make redactions should always be sought from the party to whom disclosure is to be made, and if such assent is not forthcoming, an application should be made in good time to the DIFC Court or tribunal for permission. It is invariably better to disclose redacted materials within time and to retrospectively secure assent or permission than to delay the whole disclosure process, and it is never a good idea to disclose unredacted materials and then to seek permission to redact the same documents.

Thirdly, a confidentiality club. Such clubs are agreements to restrict access to documents to certain entities, such as the parties' lawyers and their experts, but not the parties themselves. They are used most commonly when documents are disclosed which have confidential information in them, e.g. commercially sensitive information that may be taken advantage of by the opposing side. A confidentiality club can be used to restrict the dissemination of information and may tip the balance when providing the adequate safeguards for the processing of personal data as the data protection law requires. The existence of a club on its own and without any other legal measure would likely not provide a sufficient basis for processing and/or disclosure of information, but if the arrangement were to be approved by a Court order, then the Article 11(f) grounds may be established.

Finally, there are the legal concepts of privilege and 'without prejudice' communications. If parties have a genuine fear that the documents they are obliged to disclose may lead to liability under an applicable data protection regime, parties should consider whether they can claim privilege over the documents that are being sought. Privilege does not extend to documents merely because they contain personal data or special categories of personal data, of course, but it is certainly worthwhile bearing privilege in mind. Alternatively, parties may also consider avoiding the possibility of documents ever being subject to publication by exchanging those documents through the mechanism of 'without prejudice' communications, in which the parties agree to open up a corridor for communications where neither the existence of the corridor nor the subject matter of the communications ever goes before a Court or tribunal. Because such communications could only be genuine attempts to negotiate or settle a dispute, they are arguably protected also by the grounds at Article 11(f) in the case of special data, or under Articles 33(3)(b) and 35(3)(b), which go to the ability to resist DSARs where personal data is needed for the establishment, exercise or defence of legal claims, and/or Article 35(3)(d), which allows the processing of data and resisting DSARs for a 'substantial public interest', which includes the administration of justice and the exercise of a function conferred by an applicable law.

Conclusion

Just as the Previous Data Protection Law was replaced with the New Data Protection Law in the DIFC, the ADGM Regulations are expected to be replaced in the near future with new regulations to make the ADGM's legal regime akin to the EU General Data Protection Regulations.

Given the multiplicity of forms of dispute resolution in the region, it is conceivable that the interaction between the ADGM and DIFC data protection regulations and dispute resolution processes will be examined by a Court, and that further authoritative guidance may be provided to data protection and disputes lawyers.

For further information, please contact Peter Smith (p.smith@tamimi.com) or Martin Hayward (m.hayward@tamimi.com).

Criminal penalties for dishonoured cheques after legislation is repealed in UAE

Mohamed Al Marzouqi
Deputy Managing Partner
Litigation
m.almarzouqi@tamimi.com

On 26 October 2020, the local press published news that the cabinet of UAE approved the proposed amendments to the Commercial Transactions Law ('CTL'). According to the press release, this decree approves fundamental amendments regarding matters relating to cheques, notably the repeal of Articles 401, 402, and 403 of the Federal Penal Code which provide punitive provisions for offences involving cheques. The amendments to the Commercial Transactions Law (Federal Decree Law 14 of 2020) was published in Federal Gazette supplement 687 dated 20 September 2020.

Given the nature of commercial transactions in the UAE, the cheque has been the ideal and preferred instrument of payment and credit for merchants and banks. The cheque is also the preferred instrument for individuals in their daily transactions, given the exemplary legal protection it enjoys when seeking redress in the criminal courts of the UAE.

The criminal justice system supports commercial transactions. The use of cheques as an instrument of credit in credit and instalment sales helps drive commercial transactions. However, the tremendous pressure on law enforcement agencies and their massive case backlog has proven to be a significant burden.

There have been several attempts to pass criminal legislation to address the issue, starting with Federal Law No. 34 of 2005 which amended Article 401 of the Penal Code by adding a third paragraph stating that "The criminal case shall lapse if payment or waiver occurred after the crime was committed and before a final judgment has been delivered in the case. If this occurs after the judgment becomes final, its enforcement shall be stayed." In this way, the drawer can avoid penalties by paying the full value of the cheque or settling the matter, which in the past was not an option, especially once a final judgment had been delivered in the criminal case. With such amendments in place, convicted persons have been more inclined to settle their cheques, thereby reinforcing the position of the cheque and creating more confidence among creditors who are more concerned about recovering their debt as opposed to seeking legal redress per se.

Further amendments were made to criminal legislation in 2018 i.e. the Criminal Procedure Law (Decree Law No. 17 of 2018) which introduced the penal order, a previously unknown facet of the criminal justice system of the UAE. A penal order is a judicial order issued by the Public Prosecution for various minor offences, including bounced cheques, as a judgment of the criminal court in order to save time by bypassing the normal court procedures. Although this had a positive impact on the accused and helped ease the burden on the courts, the status of earlier issues remained the same.

New provisions introduced by the amendments to the Commercial Transactions Law

The law, has now been approved by the Cabinet, and the President of the UAE. It is important to highlight its most prominent features.

The provisions amend Articles 600, 641, 642, 643, and 644 of the current law.

Partial payment

The press release mentioned that the most important of these amendments is the requirement that banks accept partial payment of the value of the cheque if its full value is not available in the drawer's account.

The concept of partial payment is not new to the Commercial Transactions Law. Article 617(3) of the current law provides: "If the funds for payment are less than the cheque amount, the bearer shall demand from the drawee to make partial settlement to the extent of the amount available with him, and shall ask him to endorse such payment on the back of the cheque and to give him a certificate to this effect. The right of recourse for the balance amount shall be established either by this certificate or by making a protest."

In practical terms however, this provision has not been implemented by the banks which, in their view, has been due to certain impediments despite several circulars issued by UAE Central Banks to banks.

The current provision in the law, although explicit, has no compelling requirement for banks to accept partial payment and issue a relevant certificate to the holder of the cheque. For this reason, a fine has been added as a penalty against any bank that refuses to render partial payment of a cheque or issue a relevant certificate.

The Cheque return receipt: a writ of execution

The newly introduced provisions treat the insufficient funds' notice of the drawee as a writ of execution according to the executive regulations of the Civil Procedure Law. This dispenses with the need to obtain a judgment or order from the competent court. Instead, direct recourse is now available to the execution judge for compulsory enforcement against the drawer. This is a departure from the accepted practice regarding writs of execution which. as a bare minimum, would normally need to be approved by a public officer. It is important to note that the executive regulations recognise the specific documents which the law considers to be a writ of execution, although this is not applied in practice given the risk of putting acts under private signature in force as writs of execution on an equal footing as court rulings and orders.

The current regime allows the bearer of the cheque to obtain, from the Judge of Summary Matters, a payment order for

commercial papers, including cheques. These too, are fast track procedures, but taken under the supervision of the courts, leaving the execution courts to deal only with enforcement related disputes within narrow limits. The new amendments however, addresses this by stating that related disputes and enforcement procedures shall be in accordance with the rules set out in a Cabinet decision which will follow the issuance of the law. It is hoped that these rules grant the execution judge the authority to deny compulsory enforcement in cases where fraud is evident or the drawer has paid the full value of the cheque.

How do amendments to the new Commercial Transactions Law affect the legal accountability of cheques? A key change is that it will help prevent criminal lawsuits, with specific exceptions.

Amended scope of penalties for Cheques

As noted, the new amendments repeals Articles 401, 402, and 403 of the Penal Code dealing with cheque offences. The new amendments has narrowed the scope of prosecution of writing bad cheques, and instead lists specific cases which are prosecutable. In other words, not every bounced cheque can be the subject of a criminal complaint. There are specific criteria that must be fulfilled under the amended law.

Article 641 bis 1 limits the scope of prosecution to any person who endorses a cheque in favour of another or gives him or her a bearer draft, knowing that there is no sufficient balance to honour the cheque or that it is not drawable. The same article prescribes imprisonment and a fine as a penalty for any drawer who orders the drawee, before the date of encashment, not to cash the cheque or withdraws its entire balance before presenting it to the drawee, or deliberately writes a cheque in a way that prevents it from being cashed.

Cheques issued by corporate entities

Under the current regime, the signatory of the dishonoured cheque bears criminal and civil liability jointly with the corporate entity. The relevant principles laid down by the courts presume that the authorised signatory knew that there was insufficient balance in the account of the corporate entity when the cheque was issued or on its due date. The amendments to the Commercial Transactions Law have removed such liability from the corporate entity's authorised signatory and limited the penalty to a fine for the corporate entity in addition to ancillary penalties such as a six-month suspension of their licence and its revocation in the event of a repeated offence. The amendments expressly provide that the authorised signatory incurs no liability unless he or she is proven to have had knowledge of the offence or committed the same for his or her own ends or those of another. The authorised signatory's knowledge of the offence will be difficult to prove in practice unless it is clear that the authorised signatory is the one who ordered the bank not to cash the cheque or to close the account before the cheque's due date, which the creditor can only prove through the drawee bank; a very difficult proposition indeed given the bank's confidentiality obligations to its clients.

The introduction of new penalties

The amended law has introduced criminal penalties for violating the law and stipulates a fine for falsely declaring a lack of sufficient funds to cover a cheque or refusing, in bad faith, to honour a cheque drawn on the bank, or refraining from rendering partial payment of a cheque.

The new amendments also provide for a penalty against a bank in the form of a fine in the event they fail to comply with any ancillary penalties the courts may issue against the convicted person in terms of suspending their cheque book privileges for a period of time as set out by the judgment.

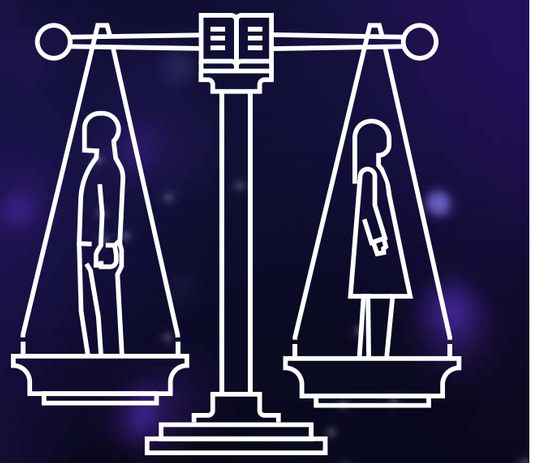
Grace period for adjustment of status

The law provides for a one-year period from the date of its publication for the law to come into effect. This period, in the opinion of legal practitioners, is insufficient for banks and companies to put in place measures to safeguard against dishonoured cheques.

It is expected the initial stages of the application of the new amendments will bring about uncertainty however, it is also expected the new amendments will offer new forms of protection for credit-based commercial transactions.

For further information, please contact Mohamed Al Marzouqi (m.almarzouqi@tamimi.com).

Your law or mine? The UAE overhauls personal status laws and reaffirms its openness



Dipali Maldonado
Senior Counsel
Private Client Services
d.maldonado@tamimi.com

Ahmed Zohny
Senior Associate
Private Client Services
a.zohny@tamimi.com

The United Arab Emirates is a cultural melting pot of over 200 nationalities and has an expat community comprising c. 90 per cent of total population. The UAE government is constantly undertaking initiatives, in line with its principles of tolerance, coexistence and acceptance of the other, to provide a more attractive living environment for expatriates. The latest such endeavour undertaken by the UAE government is the introduction of amendments to several articles in federal laws relating to marriage, separation, and divorce. These amendments aim to allow for the application of foreign laws with regard to these issues.

Below we set out a summary of the main changes whilst also providing our analysis on their potential practical application and ramifications.

The new amendments

Previously, the UAE Personal Status Law No. 28 of 2005 (the 'PSL'), which is based on Islamic Sharia principles, would have applied to all divorces in the UAE, whether between Muslims or non-Muslims, UAE nationals or expats. A party could petition the UAE court to apply the law of their nationality, with the law of the husband's nationality taking precedence.

The recent amendments have introduced a significant change whereby rather than the law of nationality; the marriage would instead be governed by the law of the country in which the marriage took place. Indeed, the law of the place where the marriage was performed would not only govern the validity of the marriage but also any ensuing divorce and financial elements, including division of assets and alimony.

This is significant in today's world where many couples opt for a destination wedding, outside of both their country of nationality and/or residence.

What do these amendments mean for expatriates?

The amendments open up a gateway for expatriates to request the application of either the law of where their marriage was performed or alternatively, the PSL that is based on Islamic Sharia principles (as before) to matters related to marriage, separation, division of assets and divorce. It paves the way for divorce law forum shopping, such that a party has a wider option to choose the law that is more favourable to them given their individual circumstances.

However, it is important to note that this option is neither absolute nor guaranteed.

By default, as per Article 1 of the PSL, the UAE PSL shall apply to expatriates with regard to the personal and financial effects of marriage, separation, or divorce, unless one or the both spouses insist on the application of their law of citizenship. But a request to apply the law of citizenship must not contradict Article 13 of Civil Transactions Law No. 5 of 1985 (the 'CTL').

Article 13 of the CTL provides that the law of the state where the marriage took place shall govern issues related to marriage, separation, or divorce, that would result in the fact that the law of citizenship will only apply if the marriage took place in the same country of citizenship of the spouse(s) requesting the application of their law. Otherwise, the law of the country where the marriage took place will apply even if it is not the country of citizenship.

Many couples of the same or of different nationalities have tied the knot at popular locations other than their country of citizenship, not knowing that the laws of where they got married could govern their marriage and divorce in the UAE. In light of the newly introduced amendments that came into effect as of 1 October 2020, this is the new and perhaps unexpected reality of getting married in exotic locations such as the Maldives, Seychelles, Greece, Bali or other such romantic destinations.

In summary, the options for expatriates regarding the applicable law as per the new amendments will either be the UAE PSL No. 28 of 2005 or the law of where the marriage took place.

Special considerations for the application of a foreign Law

Notwithstanding the above, requesting the application of a foreign law before the UAE Courts is not a given and remains subject to two conditions:

Firstly, presenting the court with a legally attested copy of the applicable foreign law or the relevant parts thereof. For example, if the law in question regulates different aspects of the matrimonial relationship, and the case before the UAE court involves divorce and determination of alimonies, then only a copy of the relevant sections is needed. This is particularly important as the copy must be attested and it must be translated into Arabic in order to be accepted by the UAE court; this process of translation and attestation itself can be a lengthy and costly exercise.

Secondly, the law (or its relevant parts) must be straightforward and easy to interpret in regulating the disputed issues thereby enabling its direct application by the UAE Court.

However, it should be noted that in presenting only the relevant parts of the foreign law, the requesting spouse must make sure that none of the applicable articles in the relevant parts are required to be read or interpreted in light of other articles not included in the selected parts as that would render these parts inapplicable directly, hence, failing to meet the second condition.

Failure to satisfy any of the above conditions will result in the court reverting to the application of the PSL law.

Certainly, the spouse invoking the application of the foreign law will incur, depending on the circumstances, considerable effort and cost in obtaining, attesting, and translating the foreign law with no absolute certainty of its application if the foreign law fails to satisfy the second condition.

Hence why, before even filing a request for the application of the foreign law, legal consultation in both the UAE as well as the country of marriage must be sought to carefully assess the situation.

For further information, please contact Dipali Maldonado (d.maldonado@tamimi.com) and Ahmed Zohny (a.zohny@tamimi.com).

Estate and succession planning: a time to reflect

Ruksana Ellahi
Senior Associate
Private Client Services
r.ellahi@tamimi.com

The coronavirus pandemic has infiltrated all of our lives, in one way or another, without discriminating between nationality, class, culture, faith, profession or social standing. We are now getting used to living alongside the virus and to a new normal, however there was a moment when it brought the world to a standstill and with it, brought a moment to pause for reflection.

A moment to reflect on the future, to organise one's legal affairs and to focus on good estate planning. Many of our clients have come to us to assess and advise on their personal affairs in the UAE and below, we share a list of top tips to keep in mind when considering yours:

Wills

Register a Will or review any existing Will to ensure that it remains up to date and in accordance with your wishes. Wills can cover not only assets but also guardianship of minor children.

For non-Muslims, there are two well tried and tested options in the UAE to register Wills, being the Dubai International Financial Centre or the Abu Dhabi Judicial Department and for Muslims, a Sharia compliant Will can be registered before the local courts.

Trusts

As with Wills, trusts should also be considered and/or reviewed to ensure that a settlor remains happy with the assets incorporated, the financial strategy of the trust, the trustee as well as the beneficiaries.

Succession planning

Taking the time to consider a good succession plan for your business, in the event you become incapacitated, is critical to ensuring that business operations continue well and successfully into the future.

Life insurance

Life insurance falls outside of local inheritance laws and so is something worth considering putting in place since it would ensure that the named beneficiary would get an immediate cash payout which would not be delayed by the probate process. It is also worth mentioning here that, in the unexpected case of death of a bank account holder, even jointly held bank accounts, the account will be frozen and so the immediate payout of life insurance proceeds can really assist loved ones in their time of need.

A moment to reflect on the future, to organise one's legal affairs and to focus on good estate planning.

Power of attorney

Whilst the UAE does not permit irrevocable powers of attorney, it is still a good idea to review the powers and authority in place and to assess whether the attorney is still someone you would trust to carry out those powers on your behalf.

Gifts

Consider whether you wish to make any lifetime gifts which can be a good estate and/or tax planning tool providing certain criteria are met.

Tax implications

The pandemic has prevented many people from being able to return to their country of domicile and/or residency. It is important to check the tax rules of where you are or have been to ensure that the number of days spent there have not triggered any tax implications. Some tax authorities, such as the UK and OECD, have opined that the number of days spent in forced quarantine due to the pandemic will not count towards the statutory residency test but it is important to check the exact dates and rules in each country.

Documents

Best practice is always to ensure that important documents are kept in a safe and known place, thus making it easier for family members to get access to relevant information should the need arise. It is also important to ensure that such documents are legalised, attested and translated into Arabic (as applicable) as required by the UAE government and courts.

Given that so much of our lives are now online (bank and investment accounts, utility bills, emails etc.), it is recommended to have a record of these digital assets, readily accessible to family members should the need arise.

For further information, please contact Ruksana Ellahi (r.ellahi@tamimi.com).

Video gaming development in the UAE: legal issues

Fiona Robertson
Senior Counsel,
Head of Media
f.robertson@tamimi.com

Charlotte Sutcliffe
Associate
Technology, Media &
Telecommunications
c.sutcliffe@tamimi.com

Introduction

The UAE is currently ranked 35th out of 100 in world video gaming industries. The global gaming industry is now valued at $129 billion a year. That is more than the annual worldwide numbers taken in by box-office, music streaming and album sales, and major sports leagues all put together. It has been suggested that the e-gaming market in the GCC will be worth $821 million (AED 3 billion) by 2021.

The UAE Government enthusiastically pioneers to position Dubai at the forefront of innovation. Supporting video gaming ventures offers huge opportunities in the technology innovation space, and it is clear that the UAE Government is aware of that. For example, Dubai Tourism and Dubai Media Office hosts a Girl Gamer Festival where gamer girls from around the world compete to win $100K. Paul Roy, CEO of Galaxy Racer eSports said: "Hosting this event will add new value to Dubai's emergence as an innovation-driven city." Also, last year, a UAE telecoms provider launched the first-ever cloud gaming service to promote e-gaming in the region and encourage non-gamers to join the ecosystem. Etisalat identified that increased gaming means increased data usage which, in turn means, bringing in extra revenue for operators. Gaming also offers huge revenue opportunities for developers, contractors and telco companies. Clearly it is no secret that gaming is huge in the UAE!

This means huge opportunities for our technology and media clients to diversify their business. This article will provide a snapshot guide for those wishing to launch in the video gaming industry in the UAE, as well as some ways to avoid those pesky legal pitfalls.

Video game development

If you dream of becoming the next 'Epic Games', be prepared for the Call of Duty to work with a great deal of talented people with varying skills and one thing in common: the protection of their legal interests. Remember, no man (or woman!) is an island and it is unlikely that one person will possess all the skillsets needed, so you will need to engage with everyone from graphic artists, to animators, voice actors, sound engineers, software programmers, songwriters and scriptwriters.

Assuming you have a company structure, a trade name, a brand and sufficient financing, the next steps are to work with industry professionals to bring your vision to life.

Pre-development stage

The most important aspect of game development is that the you own the intellectual property rights in the finished product, and all the rights created through the development process. The best and most effective way of protecting your rights is through properly drafted contracts with all of your stakeholders. Remember however, that intellectual property law does not protect the underlying idea or concept of a video game. If you are discussing your concept with stakeholders with whom you do not yet have an agreement, you must first have both parties sign a non-disclosure agreement, and ensure to identify any materials you disclose as confidential.

Development stage: ensuring IP ownership over developed work

Through your journey, you may engage with some entities on a contractor basis, and some on an employee/employer basis. Typically, if the person is a contractor, they will own the IP in whatever they create. Whereas, if they are an employee hired by you, you will own the IP. However, in most cases, the difference between employees and contractors is not resolved by simply calling someone an employee or contractor. For this reason, you will need to express, in writing, that you own the IP in all materials, and prepare a written assignment (or broad licence) of IP to that effect.

The ownership of IP will need to be covered in every area of development. Whether or not you own or have a licence to use the developed IP and any adaptations of that IP will usually depend on how much you are paying for the development of that IP, and which party is more likely to find that IP valuable to their business venture. For example, a coder may wish to own the IP of specific routines or modules of code that augment or improve the operation of the authoring programme so that they can use those routines or modules of code in future projects.

If the game design is contained in a 'design document' which records details of the ideas, stories, worlds, characters and gameplay mechanics, you should be aware that there is copyright in the 'design document' because it is written down into material form. However, copyright protects the words used in that document to express the 'game design' rather than the ideas, concepts or stories it describes. Therefore, you are only able to protect the precise expression of the idea, and for a successful copyright claim, you will need to prove that the particular characters, stories, dialogue and mechanics of the game were copied; not just the general concept of the game.

The next stage of game development, before any coding is done, is to decide on what platform the game will operate. A platform is the operating system used by the hardware that the game will be played on, such as Nintendo, Xbox or Android. This may require obtaining a platform licence from the game console manufacturer so that coding can be developed in accordance with the right specifications. This is likely to be a standard licence with no room for negotiation.

There are huge opportunities for our technology and media clients to diversify their business and go into video gaming development. This article will provide a snapshot guide for those wishing to launch in the video gaming industry in the UAE, as well as some ways to avoid those pesky legal pitfalls.

Development stage: obtaining permissions to use existing work

If the visual images developed for your game draw upon existing images (including photos of actual buildings, cars, products or even people), you may need to obtain a licence or consent to use them in your game. For example, using a photographer's work could land you in a copyright infringement claim. In addition, using a celebrity or civilian's image could mean you are liable for misrepresentation, false endorsement or privacy related claims.

Similarly, you could face legal repercussions for using music without a licence. If the music in your video game is produced specifically for the game, you will just need to ensure you have the right to use the IP, and that the person who developed the music also did not infringe any third party's IP when he or she created the music for you. Otherwise, you will need to seek permission from the owner of existing music in order to incorporate it into your game.

Either way, it is important to recognise that each component of music is a separate piece of IP. The components include the musical composition, the lyrics (if any) and the sound recording which is synchronised with the video animation. Each component could be owned by one person, or each component could be owned by different people.

Development stage: ensuring content complies with UAE content laws

The UAE has some restrictions on the kind of content that is able to be produced. Below is a snapshot of the kinds of rules that apply:

- media content, Videos and pictures must not contain instigation about Islam; no criticism of rulers of Emirates; and no encouragement of the commission of sin or crimes, etc. Board Resolution No. 26 of 2017;
- the National Media Council provides ratings regarding video games. Gaming classifications go up to 21 years and those are games that contain references and depictions of nudity/sexual themes, references to gambling and direct use of alcohol/illegal drugs. Games that are more explicit may be banned;
- anything that suggests dangerous or anti-social behaviour, imitable acts (e.g., dangerous stunts, suicide or self-harm), instructional criminal behaviour, offensive on-camera gestures (e.g., middle fingers, chin flick, clenched fist, forearm jerk, etc.) are ill advised to say the least;
- content is not allowed to promote alcohol. The Content Res states in Article 44(7) that "No advertisement on alcoholic drinks or prohibited drugs shall be allowed by any means directly or indirectly."
- drug abuse is not tolerated in the UAE however, depictions in foreign content are usually acceptable. It would be unacceptable to depict a local person partaking in such activities, even in fictional accounts.

Post development: distribution

Now your game is complete, you own all the IP rights (or have broad rights of access to them) and you are sure your content is in line with relevant laws, you want to start distributing. Typically, there are two options:

- publisher: typically funds the development and has the rights to manufacture and market the video game; and
- distributors, retailers and online stores: with which the publisher (or indie developer) will enter retail and wholesale distribution arrangements to release and sell the video game.

However, the digital age has rocked the boat when it comes to in-person shopping. In fact, streaming services such as xCloud and PlayStation are now literally running the show. To distribute your game on such subscription services, you can register and upload your finished product. Some subscription services allow you to use their tools to assist in the development process. Be aware that you will need to sign up to the subscription service's terms (which will likely be non-negotiable). Such terms are also likely to ask for an undertaking that you own all the IP in the game you have developed (or have the right to use such IP).

Conclusion

There is a vast array of development opportunities in the video gaming industry. The UAE is an innovative and exciting place, where its Government pioneers new technologies at the forefront of gaming development. However, gaming introduces content development issues including ensuring effective IP ownership and that content respects media content laws. Insisting on written agreements with all stakeholders, and keeping creative control over the process may save you a lot of money and pain on your way to the top; so for game developers in the Middle East, having proper legal protection is far better than venturing into unchartered territory.

For further information, please contact Fiona Robertson (f.robertson@tamimi.com) or Charlotte Sutcliffe (c.sutcliffe@tamimi.com).

Sponsorship in eSports

Fiona Robertson
Senior Counsel,
Head of Media
f.robertson@tamimi.com

Charlotte Sutcliffe
Associate
Technology, Media &
Telecommunications
c.sutcliffe@tamimi.com

The 2018 World Championship for League of Legends is arguably the most popular eSport event internationally. It is an event with an average concurrent viewership of 46.65 million people. eSports is becoming increasingly popular, with an estimated 50 per cent of the world's most wealthy and influential people having invested in eSports within the last few years.

Its popularity across the Middle East is no different. The UAE is one of the Middle East's most popular gaming regions. The mobile gaming market dominates the region's gaming market when it comes to revenue, through sponsorship, advertising, and media rights it is expected to generate $1.7 billion by 2021, around 1 per cent of the total gaming market.

So, what is eSports, and what is with all the hype? eSports consist of tournaments between high ranking gamers, played in a public venue and attended by fans. They are similar in format to traditional, live sporting events in that organisations and individuals compete at the highest levels of professional gaming. If a player reaches the top, they can also earn up to seven-figure salaries through team contracts, sponsorships, and tournament winnings. However, unlike sports sponsorship, eSports is, in many ways, more accessible, dynamic and diverse due to its high level of audience interaction and the ability for it to be streamed or played anywhere.

How do eSports make money?

eSports competitions make money in ways very similar to more traditional sports game, involving a strategic mix of sponsorship and media rights.

Sponsorship

Sponsorship is, as commonly known, a promotional activity when one organisation provides an investment in the form of a financial and/or a product or service contribution to another organisation in exchange for the ability to promote their brands. This can be witnessed in traditional sports games when a carbonated beverage brand splashes its trade mark across a football field or on massive billboards around the arena, or takes a branded opportunity for a fan site or other associated event. But eSports has something a little different…

Michael Rubinelli, CEO of the New York-based international athletes' representation and sports marketing firm Mogul, stated: "One of [the] drivers of growth is eSports. Interactive gaming is the largest entertainment revenue generating vertical in the world earning more than box office and music sales combined." High profile celebrities are in agreement with that, with Canadian singer Drake announcing his co-ownership of 100 Thieves, a "lifestyle, apparel and eSports" company, and Michael Jordan investing in Team Liquid's (a prominent Dota 2 team) parent company, aXiomatic."

Sponsorship of eSports offers a significantly higher degree of publicity to brands. This is because it can be exercised through sponsoring the game developers, the events, the individual teams or the individual players. Of course, UAE sponsors need to ensure that all advertisements comply with the National Media Council's ('NMC') regulations, the Cabinet Resolution No 23 of 2017 Concerning Media Content, as well as the Federal Law No 15 of 1980 Concerning Press and Publications. They provide an advertising and media guide containing public policy guidelines which would be helpful for any brand within the UAE wishing to sponsor an event.

In traditional sports sponsorship, the sponsorship arrangement is usually between the event (e.g. NBA basketball competition) and the company (e.g. Adidas). However, in eSports, the key sponsorship agreement is between the overall tournament organiser, such as the basketball league or the football association, and the company wishing to obtain brand exposure.

It is clear big brands are getting involved. In one example, in the Multiplayer Online Battle Arena ('MOBA') category, luxury brand Louis Vuitton has collaborated with Riot Games, to implement game character "skins" (cosmetic features for in-game characters) for one game, which could be purchased with real money. Skins, which is the fashion for the gaming fantasy characters, costs players up to $25 to purchase. Louis Vuitton has also spent around 900 hours developing a trophy case for the League of Legends World Championship cup, as part of its overall engagement. Louis Vuitton has a history of designing goods for fantasy characters, and why wouldn't it, when it is able to reach a unique audience of 99.6 million viewers?

Sponsoring events

According to the Interactive Advertising Bureau ('IAB') the eSports audience tends to be higher-than-average earners which naturally implies more spending power. Therefore, participating in sponsorship for eSports provides brands with an opportunity to actively engage with thick-walleted consumers in a meaningful way. For example, MasterCard signed an events' focused deal with Riot Games in 2019. This meant MasterCard assisted with opening ceremonies and had benefits for their cardholders including backstage tours, VIP viewing with pro players, and meet-and-greets.

Contractually, the Middle East does not always have comprehensive laws to address the issue of ambush marketing. With sponsorships, in general, a non-sponsor may attempt to associate itself with an event by using communication that would lead a consumer to believe that the brand acts as an official sponsor when in fact it does not. One complicating factor in eSports, in particular,

is the amount of conflicting sponsors all engaged with the same event. For example, in 1996, Linford Christie was individually sponsored by Puma during the Atlanta Olympics. However, the official sponsor of the Atlanta Olympics was Reebok. Puma had given Linford Christie Puma contact lenses to be worn during the press conference preceding the game in Atlanta, which conflicted with Atlanta Olympics' sponsorship agreement with Puma.

Last year, Dubai hosted the world finals of the third annual Girlgamer e-sports festival at the Meydan Grandstand. The event saw nine five-player teams compete in the games League of Legends and CounterStrike Go, one of which was local in order to help promote female gamers in the UAE. Events like this include performers, radio hosts, singers and gamers. Therefore, it can be challenging to cross check sponsors and ensure they do not conflict. This is why sponsorship should be overseen by the event organiser.

In finalising contracts for specific events in the Middle East, both events and sponsors should be aware that the region has strict prohibitions on activities such as, for instance, promotion of alcohol and gambling. Contracts need to address these activities specifically to ensure that any activity by either party that contravenes the laws will have repercussions.

Exclusive sponsorship

With estimates that eSports will become a $1.5 billion to $2.5 billion business within the next few years, it is no wonder that broadcasting companies want exclusive deals. In August this year, Riot Games announced an agreement with Chinese streaming video platform Bilibili allowing it exclusive broadcasting rights to its major League of Legends global events. Bilibili will produce original streaming and on-demand video content around the competitions, and will feature content promoting retired Chinese pro players Jian "Uzi" Zi-Hao and Ming "Clearlove" Kai. It is challenging to secure exclusive broadcasting deals for eSports, as competition is fierce. Those lucky few will need to contend with even more fierce competition from sponsors and advertisers, who are looking to reach the broadcaster's 44 billion plus audience members.

Google is a company that has taken matters into its own hands. It recently released a game-streaming service called Stadia. Stadia allows people to play games through the internet without having to buy a console or high-powered computer. Additionally, Google's YouTube secured the exclusive broadcasting rights to some of the biggest eSports leagues, including the rights to broadcast the new Call of Duty League and the already-popular Overwatch League.

Sponsoring individual teams

One particularly valuable option that brands can consider is to sponsor individual gaming teams. An example might be the brand displaying their logo on the team's shirt in exchange for benefits, or co-branding the teams website. Audi was crowned the first sponsor for Future FC, an online FIFA team recently established by the Australis Group. This deal is reported to be for three years and has a reported annual value of at least $1 million.

In the context of individual teams, there are some legal and non-legal issues which may arise:

- **Shifting teams:** the nature of eSports teams is always shifting, and players are always changing. If it is important in a deal for a player to be a part of a team, it is advised to have carefully drafted terms in relation to their ongoing participation, in the manner of a 'key man' clause. Perhaps their loss will give rise to a right or termination but it may just allow for a drop in the consideration paid by the brand;
- **League disqualification:** although sponsors cannot guarantee the success of a team in any one season, they often include extra incentives in the contract based on the progress of the championship, to give incentives and motivation for players to succeed. In addition, a drop of a star player or failure to appear in a key tournament may give rise to a right to terminate or to reduce consideration.

Sponsoring individual players and personalities

With the rise in young audiences engaging online, another way brands can get involved with eSports is by involvement with the online engagement between eSports stars and their fans. Large communities of fans are already following gaming personalities which engage their fan base through livestreams or through personal channels on platforms like YouTube. With the rise of 'double screening' (i.e. think watching TV whilst scrolling through Instagram), sponsors are given another opportunity to win the attention of consumers. Perhaps the brand could facilitate the ability of fans to livestream their favourite eSport's star narration of another competitor's game.

Engaging with sponsored content

Sponsors may provide sponsored content to the eSport's stars' fans for the purchase of the sponsor's sponsored products. In exchange, the personality receives a share of the net profits of product sales derived through its affiliate code.

Similar to the other categories of individual sponsorship, whether in sport, music or otherwise, this particular type comes with its own legal risks. Contracts need to consider the following:

- **Copyright:** There may be a rivalry for ownership over copyright over sponsored content. A sponsor may want to own all the copyright associated with the content created during the sponsorship, while a gamer (or streamer) would want to retain as much as possible of his/her own brand's rights. In this case, each party should assert its rights contractually, and provide a licence to its copyright to the other party;
- **Trademarks:** rights over trademarks are easy to track as these are registered. Each party will register and keep its trademark rights and provide licenses to each other for their respective use;
- **Player Conduct:** as a lot of eSports are exploited and promoted through personalised streaming services live events are becoming increasingly popular. Either way, sponsors should keep an eye on their players' conduct, as this could cause a reputational risk to both the individual and the sponsor. Examples are a player becoming intoxicated, violent or defamatory at an event. This is especially important in the UAE and other MENA countries, where there are strict content laws and modesty norms; and
- **Incentives:** players should be incentivised by the sponsor to do well and perform well, but also to engage and connect with its audience. This can be achieved through financial incentives such as bonuses, and consequences such as termination (as discussed above). Sponsors could also require the player to agree to minimum appearance requirements which, if not adhered to, could also result in termination. As a strategy to keep players 'onside', sponsors could also encourage players to team up with other branded players instead of with players from a competing brand in any team up games.

Conclusion

eSports provide an exciting and innovative opportunity for many stakeholders. In particular, sponsors of all shapes and sizes are able to engage on a large scale with audience members rising into the billions. Broadcasters and media buyers anticipate a shift in the way gaming fans engage with content, but one thing is for sure – eSports and e-gaming is only getting bigger and more popular over time. By successfully navigating the legal sphere, sponsors can increase revenue and tackle new markets in an exhilarating new (virtual) world.

For further information, please contact Charlotte Sutcliffe (c.sutcliffe@tamimi.com).

Recent arbitration developments in East Africa

Thomas Snider
Partner, Head of Arbitration
t.snider@tamimi.com

Trade and investment between the Middle East and Africa continues to grow, and this is set only to accelerate with the coming into force of the African Continental Free Trade Area ('AfCFTA'). AfCFTA is the largest free-trade area in the world based on the number of participating countries since the World Trade Organization was formed. Broadly speaking, AfCFTA requires member states to remove tariffs from most goods and allow free access to commodities, goods, and services across the African continent. This is expected to have spill-over effects with Africa's trade partners outside the continent. For example, the Dubai Chamber of Commerce and Industry forecasts that Dubai's trade with Africa could see an annual increase of up to 10 per cent over the next five years following the implementation of AfCFTA.

With increased trade and investment between the regions, commercial disputes will inevitably follow, and many of these disputes, as with cross-border disputes generally, will be resolved through arbitration. Accordingly, it is important for arbitration users in the Middle East trading or investing in Africa to keep abreast of arbitration-developments on the continent. Two important recent developments in this regard in nearby East Africa are: (1) Ethiopia's recent accession to the Convention on the Recognition and Enforcement of Foreign Arbitral Awards (the 'New York Convention') and; (2) Tanzania's new arbitration law.

Ethiopia's ratification of the New York Convention

The New York Convention is the cornerstone of the international arbitral legal regime. It requires parties to recognise and enforce arbitration agreements and arbitration awards in their domestic legal systems, subject to limited exceptions. The New York Convention has broad coverage globally with the vast majority of states across the world having ratified the convention over the past six decades since the convention was adopted in 1958.

Until recently, one notable hold-out on the African continent was Ethiopia. This changed, however, when Ethiopia acceded to the New York Convention on 24 August 2020, thereby becoming the 165th party to the convention. Following Ethiopia's accession, the New York Convention formally came into force for Ethiopia on 22 November 2020. This is an important and welcome development for one of Africa's fastest growing economies (notwithstanding the recent internal strife Ethiopia has experienced).

Ethiopia's accession is subject to three reservations. Two of these reservations arise under Article I.3 of the New York Convention: (1) the "reciprocity reservation", i.e., Ethiopia will apply the New York Convention only to recognition and enforcement of awards made in the territory of another contracting state, and; (2) the "commercial reservation", i.e., Ethiopia will apply the New York Convention only to differences arising out of legal relationships, whether contractual or not, that are considered commercial under the national law.

The third reservation made by Ethiopia is that the Convention will not apply retroactively. While such a reservation is not expressly found in the text of the New York Convention, several other states have nevertheless made this sort of reservation (namely Bosnia and Herzegovina, Croatia, Malta, Montenegro, North Macedonia, Moldova, Serbia, Seychelles, and Tajikistan).

Ethiopia's accession to the New York Convention falls in the midst of several other accessions by African states recently, including Sierra Leone in October 2020, Seychelles in February 2020, Maldives in September 2019, and Cabo Verde and Sudan in March 2018.

Whereas Ethiopia has taken an important step at the international treaty level to bolster its arbitration framework, Tanzania has revamped its legal framework for arbitration at the national level.

Tanzania's new Arbitration Act

Whereas Ethiopia has taken an important step at the international treaty level to bolster its arbitration framework, Tanzania has revamped its legal framework for arbitration at the national level. Tanzania recently passed a new national arbitration law, the Arbitration Act 2020 (the 'Tanzanian Arbitration Act'), that came into force in February 2020 and replaces the Arbitration Act 1931.

Notably, the Tanzanian Arbitration Act is based largely on the English Arbitration Act rather than the UNCITRAL Model Law on International Commercial Arbitration (the 'UNCITRAL Model Law'), which is more commonly used by states as the template for their national arbitration law. Indeed, several other jurisdictions in Africa that incorporate (at least some elements of) common law, including Kenya, Nigeria, South Africa, and Uganda, have based their arbitration law on the UNCITRAL Model Law.

Tanzania's decision to follow the English Arbitration Act model has garnered some criticism from commentators. One concern that has been raised is that the English Arbitration Act is tailored specifically for the English legal system and that it will not be easily transplantable to another jurisdiction.

Another concern surrounds the fact that the Tanzanian Arbitration Act, like the English Arbitration Act, provides for potentially wider discretion for judicial intervention in comparison to the UNCITRAL Model Law. For example, sections 69-71 of the Tanzanian Arbitration Act provide for a more comprehensive system for the challenge of awards, relatively similar to sections 67-69 of the English Act. Section 71 in particular follows the English Arbitration Act model by effectively providing for a right to appeal a question of law determined by an arbitral tribunal to a court (i.e., "state in a form of special case to the court", which is the language used in the Tanzanian Arbitration Act). While this provision is used sparingly in the English courts, it remains to be seen whether the Tanzanian courts will follow a similar approach in this regard.

At the end of the day, however, the Tanzanian Arbitration Act incorporates the key fundamental provisions that one would expect to see in a national arbitration law. It has also made an important advancement on the institutional side by establishing the Tanzania Arbitration Centre ('TAC') for the conduct and management of arbitration (Section 77). The TAC will maintain a list of accredited arbitrators and provide educational opportunities relating to arbitration.

It remains to be seen whether the Tanzanian Arbitration Act will render international arbitration in Tanzania more attractive to foreign investors with the prospect of judicial intervention being a concern. Nevertheless, it is safe to conclude that the new law should be considered a hopeful step towards a more arbitration friendly future for Tanzania.

Conclusion

With continued growth in trade and investment between the Middle East and Africa, it behoves users of arbitration in both regions to stay on top of developments in the respective regions. The recent developments in Ethiopia and Tanzania demonstrate a commitment among African states to further enhance their legal frameworks for arbitration and may have a practical impact sooner rather than later with the continued growth of arbitration as a means of resolving cross-border disputes.

For further information, please contact Thomas Snider (t.snider@tamimi.com).

Jurisdiction Update
Iraq

Work permits and foreign employment in Iraq

Ammar Al Humairi
Associate
Corporate Structuring
a.alhumairi@tamimi.com

Mohammed Taher
Trainee Lawyer
Corporate Structuring
m.taher@tamimi.com

Due to the recent political developments in Iraq, the Ministry of Labour has increased its enforcement efforts regarding the regulation of foreign employees in Iraq. However, it has become evident that a significant number of corporations are overlooking the laws that regulate the work of foreign employees within the country. As a result, an increasing number of corporations are facing fines and other penalties for violations of the applicable Iraqi Labour Law and relevant regulations.

At the outset, it is important to understand the definition of a foreigner under the Foreigners Residence Law No. 2 of 2017. A foreigner is defined as being "any person who does not have Iraqi nationality". This definition requires foreign individuals who wish to work in the territories of Iraq to obtain work permits.

This article provides an overview of the legal requirements to obtain work permits for foreign employees in Iraq and the consequences of non-compliance in accordance with the applicable legislation.

Iraqi Labour Law prohibits foreign employees from working inside Iraq, unless he or she obtains a work permit. Employers in Iraq may apply for work permits on behalf of their foreign employees. In addition, Iraqi Labour Law obliges the employer, at his or her own expense, to provide foreign employees with paid round trip tickets to their employees' home countries, unless the employee, without a legitimate excuse,

An increasing number of corporations in Iraq are facing penalties for violations of the applicable Iraqi labour law.

leaves his or her job. Furthermore, the Labour Law requires the employer, in the event of a foreign employee's death, to do all that is required to repatriate the body of the foreign deceased employee, to his or her home country, or his or her resident country, upon the request of the said employee's relatives.

Finally, the Labour Law generally grants foreign employees, who are terminated from their jobs in Iraq, a grace period in order to obtain a new employment opportunity, by giving him or her some time to settle without being considered an illegal resident and thereby potentially subject to fines and/or deportation.

In order to obtain a work permit, initially, the approval of the Ministry of Labour is required. Prior to travelling to Iraq, a foreign employee must send the required immigration documents to the Iraqi Ministry of Labour to obtain their approval. The said documents must be accompanied by a power of attorney. Pursuant to Iraqi legislation, the percentage of foreign employees shall not exceed 50 per cent of the total staff of incorporated companies, and the remaining 50 per cent shall consist of locals.

Upon full compliance with the required conditions, the Ministry of Labour shall issue the required approval. Following this, the competent attorney shall attend the Directorate of Residence Affairs to obtain the visa for the employee, which allows the foreign employee to travel to Iraq.

After the foreign employee's entry, the competent attorney shall follow up with the Ministry of Labour within seven days as of the date of said entry, to obtain the work permit. The validity of the work permit is limited to one year, according to the valid regulations, to be renewed every year upon a request from the employer, at least one month prior to the expiry date of the work permit.

Foreign employees exempt from obtaining the work permit

According to the Instructions, the following foreign employees are excluded from obtaining work permits:

1. employees of international entities, diplomatic missions and commercial and foreign consulates acknowledged by Iraq;
2. foreign employees who are permitted by the international laws, conventions and treaties of which the State of Iraq is a member;
3. foreign employees appointed by the government; and
4. foreign employees who are recruited for less than 30 working days to work in Iraq as experts, for maintenance purposes or for technical consultations.

Violations of the Law

Iraqi Labour Law grants a judge of the Labour Court discretion in how to deal with foreign employees who come to Iraq and who work without the required legal permit. Any fines incurred shall range between three times the minimum daily wages and three times the minimum monthly pay of the employee.

With the increasing number of foreign employees in Iraq, the Ministry of Labour has become more strict regarding foreign employees and non-compliance of the employer corporations, there have been an increasing number of lawsuits filed in the Labour Court by the Ministry of Labour against such offending corporations particularly where correct work permits have not been obtained (an offence which may result in paying significant amounts of fines). In summary, it is essential for corporations in Iraq to comply with the applicable regulations with regard to obtaining work permits for its foreign employees.

For further information, please contact Mohammed Taher (m.taher@tamimi.com).

Fund schemes in the QFC: options and key highlights

Dennis Ryan
Senior Associate
Banking & Finance
d.ryan@tamimi.com

Sofian Nawaiseh
Associate
Banking & Finance
s.nawaiseh@tamimi.com

This article discusses the available schemes and funds that may be established in the Qatar Financial Centre ('QFC'). It sets out key highlights of the main differences between types of funds and their legal and regulatory requirements. This article also discusses the marketing and promotion of foreign funds in the QFC.

The QFC was established by the Government of Qatar in 2005 as an onshore business and financial centre with the objective of developing the market for financial services in the region by offering a regulatory infrastructure incorporating international best practices and standards based on English Common Law. The QFC allows 100 per cent ownership by foreign companies and all profits can be repatriated outside of Qatar. Alternatively, foreign ownership limits in Qatar formerly required a 51 per cent Qatari partner, though these limits have since been relaxed subject to certain conditions.

In 2019, investment funds in Qatar were valued at US$19.6 billion in assets under management ('AUM'), over half of which were managed by QFC-based investment managers.[1] Following the introduction of the exchange-traded funds ('ETFs') regime in the QFC, Amwal partnered with Doha Bank to launch Qatar's first ETF – the QE Index ETF ('QETF QD'), an equity fund tracking the largest and most liquid companies listed on the Qatar Stock Exchange ('QSE') and Masraf Al Rayan (managed by Al Rayan Investment)

[1] *Qatar Capital Market Report 2020, p. 5*

launched Qatar's first Islamic ETF called the Al Rayan Qatar ETF ('QATR').

The QFCRA also introduced amendments to its CIS rulebook to allow retail real estate funds, including real estate investment trusts ('REITS'). This opens up opportunities for sponsors and investors to participate in the mega infrastructure projects in Qatar by establishing and investing in infrastructure funds offering the government an alternative source of project funding.

In addition, Qatar's burgeoning shipping and aviation sectors could create opportunities for asset managers to launch domestic funds based on an investment strategy to acquire and lease these assets. Commodity funds are also an option for investing in physical gold, natural gas and oil or alternatively, in commodity indices or commodity futures contracts. Further, initiatives aimed at the private equity sector and the venture capital industry include the formation of funds with investment strategies to raise venture capital and seek angel investments for investing in Fintech and technology start-ups.

The available options for establishing a diversity of schemes and funds in the QFC evidence a dynamic and responsive regulatory environment that is focused on growth both in capital markets and private funds in Qatar.

Collective Investment Schemes

In 2010, the QFC Regulatory Authority, the main regulator of QFC funds ('QFCRA'), issued two separate rules to govern funds in the QFC:

i. the Collective Investment Schemes Rules 2010 ('COLL'); and

ii. the Private Placement Schemes Rules 2010 ('PRIV').

The QFC Financial Services Regulations define "collective investment schemes" as any arrangement the purpose of which is to enable persons taking part in the arrangements (participants) to participate in or receive profits or income arising from the acquisition, holding, management or disposal of property or sums paid out of such profits or income.

Typical of other jurisdictions in the region, QFC collective investment schemes must generally meet the following conditions:

in relation to property:

1. the arrangement is made with respect to property of any description, including money, whether the participants become owners of the property or any part of it or otherwise; and
2. none of the participants have day-to-day control over the management of the property, whether or not they have the right to be consulted or give directions in respect of the property;

in relation to investment:

1. the contributions of the participants and the profits or income out of which payments to be made are pooled; or
2. the property is managed as a whole by or on behalf of the operator of the scheme.

COLL provides that a person must not operate a collective investment scheme that is established in the QFC unless it is registered under COLL or PRIV.

Collective investment schemes may be established in the QFC in a number of legal forms which include:

i. collective investment companies ('CIC');

ii. collective investment partnerships ('CIP');

iii. collective investment trusts ('CIT'); and

iv. other legal forms permitted by the QFCRA.

Collective investment schemes governed under COLL consist of two categories:

i. retail schemes; and

ii. qualified investors schemes.

The QFC has a well-established funds regime which was first introduced in 2007.

As the name of the two different schemes suggests, the dividing line between them is the type of investors that may participate in the schemes. Only "qualified investors" are eligible to buy units in qualified investors schemes.

A "qualified investor" is a person who is a business customer or a market counterparty of an authorised firm in relation to dealings in investments that consist of (or include) units in the scheme. Business customers and eligible counterparties are classified as follows:

Business customers include:

1. collective investment schemes;
2. a corporate body, a corporate body that has a holding company, a partnership or unincorporated association, all of which have or have had at any time during the previous two years, called-up share capital or net assets of at least QAR 18 million (approximately US$5 million) (or its equivalent in any other currency at the relevant time) or an annual net turnover of at least QAR 30 million (approximately US$8.2 million);
3. a trustee of a trust that has or has had at any time during the previous two years, assets of at least QAR 18 million (US$5 million) (calculated as the total value of the cash and investments that form part of the trust's assets, without deducting its liabilities);
4. a customer classified as a business customer who:
   i. has asked to be classified as a business customer;
   ii. after a determination, the authorised firm is satisfied that the customer has not less than QAR 4 million (approximately US$1.1 million) in net assets; and
   iii. the authorised firm is satisfied that the customer has sufficient knowledge, experience and understanding of the relevant financial markets, products and transactions and their associated risks to justify the firm's dealing with such customers without the benefit of the retail protections.

Eligible counterparties are:

1. an authorised firm in the QFC;
2. a regulated financial institution;
3. an eligible clearing house or eligible exchange;
4. a government, government agency, or central bank or other national monetary authority, of any jurisdiction;
5. a state investment body, or a body charged with, or intervening in, the management of the public debt;
6. a supranational organisation, the members of which are jurisdictions, central banks or national monetary authorities.

A retail investor is neither a business customer nor a market counterparty and may not participate or buy units in qualified investors schemes. Qualified investors on the other hand, may participate in qualified investors schemes as well as retail schemes.

COLL imposes heightened protection requirements for retail investors schemes to protect the interests of retail investors who do not possess the same level of knowledge and expertise in relation to the financial markets and the risks of investment as qualified investors.

Set out below is a table outlining the general characteristics and main differences between the two categories of collective investment schemes that are established under COLL.

Type of scheme	Eligible investors	Legal form	Level of regulation	Investment and borrowing restrictions
Retail scheme	Retail and qualified investors	CIC and CIP only	Intense level of regulation, based on the European Union Directive for Undertakings for Collective Investment Schemes in Transferable Securities (UCITS)	Concentration limits and borrowing is restricted to 10% only of the scheme's properties
Qualified investors scheme	Qualified investors only	Any legal form	Lighter level of regulation and oversight	No concentration limits and borrowing is allowed up to 100% of the scheme's properties

Particular types of funds

Property funds:

A property fund is a scheme that is dedicated to investments in immovable assets and in securities issued by corporations whose main activities are investing in immovable assets, where the operator of the fund has to appoint an independent valuator, whose role is to perform periodic valuations of the immovable assets.

The QFCRA imposes additional requirements for retail property funds. For example, 75 per cent of the gross asset value of a retail property fund must at all times be invested in at least three immovable assets that generate recurrent rental income. By contrast, qualified investors' property funds have no such investment limits. On borrowing limits, the operator of a retail property fund is obliged at all times to ensure that the fund's total borrowing does not exceed 50 per cent of the fund's gross asset value.

REITs:

Real estate investments trusts ("REITs") are retail property funds established in the QFC and have the following characteristics:

1. the fund must be a closed-ended fund;
2. the fund is listed on the Qatar Stock Exchange or another regulated exchange;
3. the fund's constitutional document and prospectus state that:
   i. the fund will not invest in vacant land;
   ii. 75 per cent of the fund's assets will be invested in income-producing immovable assets; and
   iii. the fund will distribute to unit holders at least 80 per cent of its audited annual net income, and
   iv. the fund must provide a guarantee of the fund's income, covering the first five years of the fund's operation, from income-producing immovable assets.

Islamic funds:

Islamic funds, which are based on Sharia principles, may be established under COLL. Islamic funds must comply with additional requirements including:

1. the constitutional documents of the Islamic fund must include a statement that it is an Islamic fund and consequently that its entire business operations are conducted in accordance with the principles of Sharia and a statement providing the details of the Sharia supervisory board;

2. the operator of an Islamic fund must keep all financial accounts and statements of the fund in accordance with the accounting standards of the Accounting and Auditing Organisation for Islamic Financial Institutions; and
3. the operator of an Islamic fund must ensure that there is at all times a Sharia supervisory board for the fund.

Master- feeder and fund in funds structures:

Feeder funds are funds established in the QFC and are dedicated to investments in another single scheme. The prospectus of feeder funds must include the following additional information:

1. a prominent risk warning to alert participants to the fact that they may be subject to higher fees arising from a layered investment structure; and
2. details of the fees arising at the level of the feeder fund itself and the scheme (or sub-scheme) to which its investments are dedicated.

Similar additional information is required to be added to the prospectus of a "fund in funds", which is a scheme that is dedicated to investments in two or more schemes or sub-schemes.

Private placement schemes

Private placement schemes are separately regulated under PRIV. Private placement schemes share the main characteristics and requirements of collective investment schemes. These funds, however, cannot be offered to the public. Instead, the units in these funds are offered exclusively to qualified investors not exceeding (at any time) 100 participants. Examples of private placement funds are hedge funds and private equity funds.

As discussed above, the level of regulatory requirements and QFCRA's oversight over different types of funds differ depending on the nature of the investors (participants). Given that private placement funds are directed to selected qualified investors, the degree of protection and regulatory

The available options for establishing a diversity of schemes and funds in the QFC evidence a dynamic and responsive regulatory environment that is focused on growth both in capital markets and private funds in Qatar.

requirements is more flexible than funds established under COLL. For example, all schemes registered under COLL must appoint an independent entity that is responsible for safeguarding the scheme's property to ensure (for example) that all of the scheme's property is properly accounted for and is clearly identified as the scheme's property, as well as overseeing the operator of the fund to ensure it is managing the scheme in accordance with requirements of COLL, the scheme's constitutional documents and the latest filed prospectus. Alternatively, schemes established under PRIV are not required to appoint an independent entity. Rather, private placement schemes are required to appoint an independent custodian, that is responsible to hold the property of the fund. It is important to note, however, that an independent custodian does not perform any oversight function on the operator of the fund as required under COLL.

Non-QFC schemes

A non-QFC scheme is a scheme that is not established in the QFC. COLL allows firms authorised in the QFC to promote and offer units in non-QFC schemes. However, COLL imposes a number of requirements to be satisfied by such firms in order to be able to promote non-QFC schemes. For example, a QFC authorised firm may not approve or promote a non-QFC scheme unless the scheme has a written constitution and a written prospectus. The authorised firm must provide a prospectus and a complying disclaimer to a customer before the customer becomes contractually bound to the sale of the collective investment scheme units. A complying disclaimer, to be provided to customers for non-QFC schemes, must be in writing and must state that the scheme is not registered in the QFC or regulated by the QFCRA, the prospectus of the scheme and other related documents have not been reviewed or approved by the QFCRA, that investors' access to information may be limited in comparison to schemes registered in the QFC and recourse for the investors may also be limited and hindered and such recourse may have to be pursued in foreign (non-QFC) jurisdictions.

Similar to QFC schemes, non-QFC schemes are also subject to further and additional requirements based on the type of investors eligible to invest in the scheme. Generally, a QFC authorised firm may only promote non-QFC schemes to qualified investors. Offering units in a non-QFC scheme may not be approved by a QFC authorised firm if it is addressed to or likely to be disseminated to a retail investor. The QFCRA may declare certain schemes to be non-QFC retail schemes, which may be promoted to retail investors. In such cases, a non-QFC retail scheme would be declared in a written notice published by the QFCRA on an approved website. However, in the absence of such a declaration, authorised firms may only promote non-QFC schemes to qualified investors.

A QFC authorised firm is also subject to certain disclosure and record keeping requirements in relation to making promotions and conducting investment activities "in or from" the QFC related to units in non-QFC schemes. Such requirements include filing quarterly returns to the QFCRA containing the basic information about the non-QFC scheme, and retaining copies of the prospectus, the complying disclaimer, and any version of such documents for at least six years from the date that such documents were made available to the customers.

Conclusion

The funds regime in the QFC is well established and provides various options of fund types and legal forms to be set up in the QFC. As stated above QFC schemes may be retail investors schemes, qualified investors schemes or private placement schemes. Each type of scheme is subject to different levels of regulatory requirements, depending on the type of investors and their risk profiles.

The QFC also addresses the opportunity to market and promote non-QFC schemes in the QFC by QFC authorised firms. Subject to certain requirements, authorised firms in the QFC may promote and offer units in collective investment schemes that are established in foreign jurisdictions (outside of the QFC).

For further information, please contact Matthew Heaton (m.heaton@tamimi.com) or Dennis Ryan (d.ryan@tamimi.com).

THE 2020 HEARTBEAT OF HEALTHCARE IN THE MIDDLE EAST

Andrea Tithecott
Partner, Head of Healthcare and Regulatory
a.tithecott@tamimi.com

This year's 7th annual healthcare edition of Law Update looks at developments over the past year in the healthcare sector across the Middle East.

Amidst the plethora of COVID-19-related legislation, one would be forgiven for thinking that nothing else has happened in the field of medicine, but this is not so. The region continues to focus on healthcare transformation. The United Arab Emirates' objective to develop medical tourism remains a key part of the healthcare strategy. In the Kingdom of Saudi Arabia, its Vision 2030 transformation plan has continued to charge forwards, with the healthcare projects' market continuing to be very active despite COVID-19. Our healthcare practice experts have been exceptionally busy supporting our clients' understanding of the COVID-19 regulations but also the broader suite of regulatory change as the region continues to expand healthcare provision and the shift to digital health.

This edition contains 16 articles covering a wide range of healthcare topics across the Middle East. In the United Arab Emirates ('UAE'), we have observed another busy period of regulatory output from the regulators, including the Ministry of Health and Prevention's executive regulations to the federal law on information communication technology in healthcare elaborating on the establishment and regulation of the central healthcare IT system (page 121), a new resolution concerning the UAE medical liability law, establishing the supreme committee on medical liability (page 107), as well as regulations issued at the local health authority levels. A full summary of key UAE healthcare regulatory developments is on page 111.

The flurry of new Abu Dhabi Department of Health circulars and legislation this year included a much-anticipated new telehealth standard, to bring the same in line with the 2019 federal guidelines (page 93). We also take a look at the essential real estate requirements for establishing a hospital in the UAE (page 117). With the increasing move to online content and ecommerce, we examine the regulatory framework with which social media influencers must comply in order to market, promote, or engage in commercial activity through social media networks (page 125) as well as licensing requirements for selling healthcare products online (page 89). The protection of pharmaceutical innovations in healthcare continues to be of paramount importance to healthcare companies in the GCC (page 103), as well as fighting pharmaceutical counterfeits in the market, which have surged during the COVID-19 pandemic (page 99).

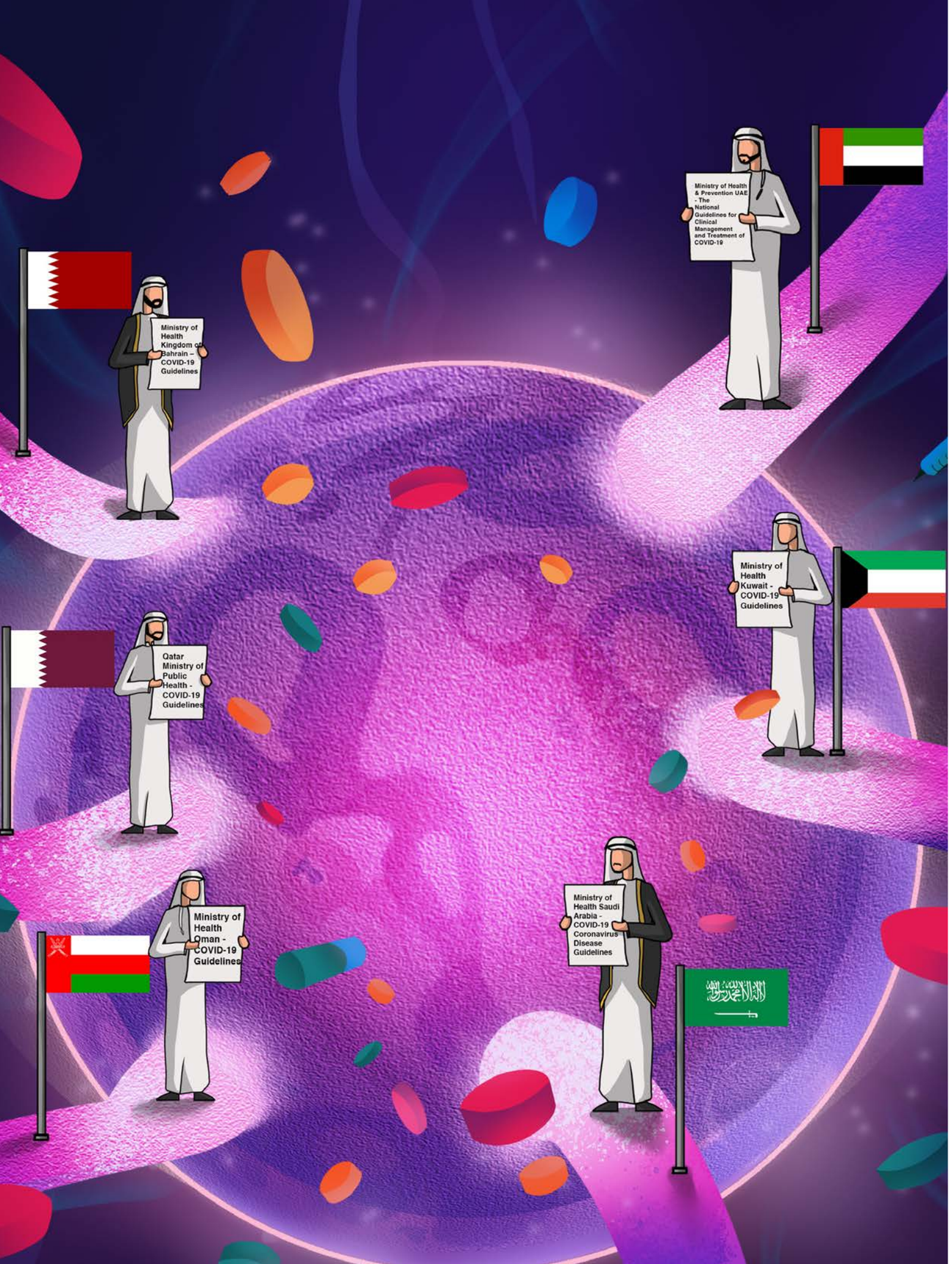
In the Kingdom of Saudi Arabia, we examine what has been achieved so far and the developments made to date with regard to Vision 2030 (page 83).

In the Kingdom of Bahrain, we examine the public health law and ways that authorities have utilised it to combat COVID-19 (page 59), and in the Sultanate of Oman we highlight the key elements of the executive regulations on the pharmacy law concerning the practice of the pharmacy profession and pharmaceutical establishments (page 73).

The State of Kuwait imposed new regulations this year concerning the registration of herbal medicines and teas, providing a much needed classification scheme (page 69). Further, in the State of Qatar we review the key elements of the compulsory contract tracing system and its legal basis, as well as associated data protection laws (page 79).

Finally, in Jordan we take a look at recent regulation concerning the licensing of pharmaceutical establishments, which has contributed to the development of an increasingly robust legislative environment for the healthcare industry (page 65).

We hope that you enjoy this special edition of Law Update. Al Tamimi's specialist healthcare lawyers across our 17 offices in nine jurisdictions regularly advise on legal and regulatory matters concerning the healthcare sector. For more details on our offering and how we can assist you, please contact us at healthcare@tamimi.com.



2020 – The year of COVID: a look at the Middle East

Andrea Tithecott
Partner, Head of
Healthcare and Regulatory
a.tithecott@tamimi.com

The year 2020 has been dominated by the COVID-19 pandemic. The Gulf Co-operation Countries, despite their enormous wealth and power, are not immune but in many respects very fortunate in dire circumstances such as these to have the kind of governmental structures and financial resources to mobilise quickly and put in place measures for the health and welfare of their citizens.

Since March 2020, the Gulf governments have issued in excess of 500 pieces of legislation, circulars, and guidance documents to fight the virus and ensure the safety of their respective populations. In parallel, economic stimulus, and business relief packages were swiftly made available to protect the business community. A selection of links to helpful sources of information can be found in the accompanying table.

Table 1: Useful Links to COVID-19 health authority resources in the Middle East.

United Arab Emirates • https://www.mohap.gov.ae/en/MediaCenter/Pages/news.aspx (The National Guidelines for Clinical Management and Treatment of COVID-19 (MOH)) • https://www.dha.gov.ae/Covid19/Pages/home.aspx (Home Isolation and Quarantine Guidelines during Coronavirus (COVID-19) Pandemic (DHA)) • https://doh.gov.ae/COVID-19 /Media%20 Center/Publications (DOH)	**State of Qatar** • https://www.moph.gov.qa/english/mediacenter/Announcements/Pages/default.aspx (Qatar Ministry of Public Health) • https://www.qchp.org.qa/en/Pages/AllCirculars.aspx (Qatar Council For Healthcare Professionals)
State of Kuwait • https://corona.e.gov.kw/en (Ministry of Health - Kuwait)	**Kingdom of Saudi Arabia** • https://www.moh.gov.sa/en/Ministry/MediaCenter/Publications/Pages/covid19.aspx - Ministry of Health (Saudi Arabia)
Sultanate of Oman • https://moh.gov.om/en/web/dgpadc/-11 (Ministry of Health Oman)	**Kingdom of Bahrain** • https://www.moh.gov.bh/HealthInfo/Publications (Ministry of Health – Kingdom of Bahrain)

The region remains hugely ambitious and committed to the development of world-class healthcare delivery systems for the population.

The ministries of health in each of the Gulf countries have taken the lead on pushing through urgent legislation, often in collaboration with other departments or sectors: for example, reaching through to overlap with employment regulations, enabling return-to-work for many; supporting other sectors, such as construction, enabling infrastructure projects to continue, thus fuelling the economy; and in recent times, issuing safety protocols enabling the aviation sector to recommence flights, and hotels to re-open allowing for 'staycations' for those still unable to travel. There are now 'drive-thru' COVID-19 testing stations for those who require regular tests to be able to return to the workplace, or to catch a flight. Simply download the 'App' on a cell-phone and await the result.

It is said the necessity is the mother of invention. The healthcare sector has witnessed a tsunami of innovation and transformation this year on a scale not previously seen in the Gulf. To list a few examples: the world's largest COVID-19 testing laboratory built in Abu Dhabi in only ten days; the launch of research studies and clinical trials to find a vaccine, with huge resources being ploughed into these projects; and new fast-track procedures for registering

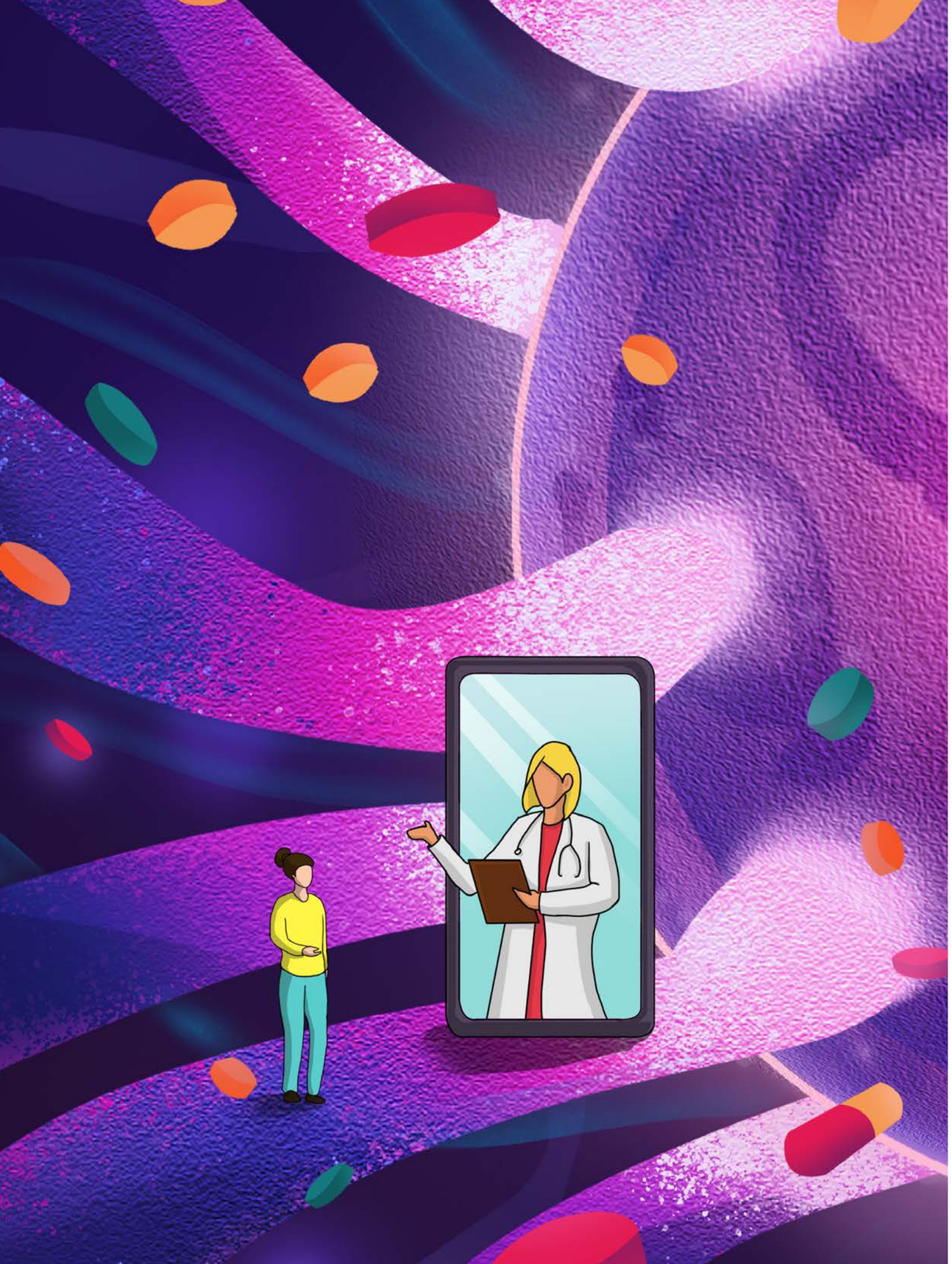
Since March 2020, the Gulf governments have issued in excess of 500 pieces of legislation, circulars, and guidance documents.

and importing medical devices (ventilators) and pharmaceuticals that have COVID-19 treatment benefits, enabling quicker delivery times to hospitals.

Meanwhile, there has been a shift over to digital health, telemedicine, e-prescribing and delivery of medicines to patients in their homes. The region had already been moving in this direction but the pace of change was slow and supporting regulation fragmented. The COVID-19 pandemic has been the catalyst for the issuance of new telemedicine laws and standards, and much quicker routes of approval (or temporarily lifting approval requirements) to enable operators to move to digital care delivery models.

The region remains hugely ambitious and committed to the development of world class healthcare delivery systems for the population. With the Arab Health Conference postponed until June 2021, it is expected that the world and the region will have made significant strides in tackling COVID-19 , to enable the event to take place safely and be the great success it has always been in connecting the region's healthcare sector. Our healthcare team look forward to connecting with our clients and friends at the next Arab Health Conference.

For further information, please contact healthcare@tamimi.com.



Acclimating to the new world order in Bahrain: the realignment of public health priorities post-COVID-19

Foutoun Hajjar
Partner, Head of Office - Bahrain
Corporate Commercial
f.hajjar@tamimi.com

Hussain Osman
Trainee Lawyer
Intellectual Property
h.osman@tamimi.com

When COVID-19 brought the world to a standstill, the Kingdom of Bahrain sought to adjust its current regulatory standing by adopting a set of measures aimed to expedite drug delivery, ensure pharmaceutical product safety during freight, and enable the adoption of tele-health solutions in light of social distancing. Furthermore, in September 2020, the Bahrain Medical Society ('BMS') took a quantum leap by adopting the World Health Organization's Occupational Health Charter in order to safeguard the physical and mental well-being of the Kingdom's key asset – the human resource.

This article considers the National Health Regulatory Authority of Bahrain ('NHRA') 'mayday' measures stemming from the broader provisions contained within Law 34 of 2018 promulgating the Public Health Law (the 'PHL'). Furthermore, an introduction to Bahrain's efforts towards institutionalising the provision of mental healthcare through regulating the functions and requirements of incorporating rehabilitation facilities will be briefly touched upon.

A blessing in disguise: applying the PHL to combat COVID-19

The flexibility of the PHL was most visible recently during the wake of the pandemic. Article 44 enables the Ministry of Health ('MOH') to exercise broad executive powers in combating the spread of all communicable diseases, by granting it a prerogative to establish adequate measures pertinent to each outbreak. This provision allows the MOH to tailor its policies on a case-by-case basis, depending on the nature of the pandemic.

Furthermore, the PHL vests the MOH with powers to install specific standards aimed both at preventing the transmission of infection across medical institutions, and the contamination of the environment. This protects the public from diseases that may originate from healthcare institutions, and offers security to patients who are hospitalised because of an unrelated condition, thereby safeguarding all members of the public irrespective of levels of vulnerability. Moreover, the elastic nature of the legislation governing public health allowed for the creation of mobile medical units across Bahrain to examine people in their homes.

The PHL dedicated key reporting mechanisms to illustrate the hierarchy of responsibility in relation to reporting an infected individual, ranging from the physician to the relatives of the patient. Further, Article 39 provides a list of all parties responsible for reporting a suspected case of a communicable disease to help prevent its spread. Moreover, any person who is infected or is suspected of being infected with a communicable disease must be isolated at a hospital or at a location as determined by the MOH.

Procedures for importing non-registered medicines and pharmaceutical products

In line with Resolution 32 of 2020 on Pharmaceutical Product Registration System and Prices, the NHRA swiftly issued Circular 41 of 2020 setting out the conditions and requirements of importing pharmaceutical products that are currently not registered. As the world witnesses a current hike in R&D activity attributed to the global call to 'find the vaccine', many inventive biologic and conventional drugs are expected to enter the local Bahraini market. Moreover, this modern pathway to import emergency drugs was highly commended by the international community as it offers a legitimate track to obtain vital interventions, thereby catering to distressed patients seeking a lifeline while combatting the logistical interruptions due to the current pandemic.

The following conditions are to be met in order to import non-registered medicines and pharmaceutical products by Public and Private Medical Hospitals ('PPMH'):

1. the PPMH must provide sufficient evidence that no registered alternative medicine or pharmaceutical product is available in Bahrain;
2. the medicines or pharmaceutical products are registered with the Gulf Health Council or with one of the countries of the Gulf Cooperation Council for the Arab Gulf States;
3. the medicines or pharmaceutical products are identifiable or registered with any of the following reference health product regulatory authorities:
   i. (FDA) - US Food and Drug Administration;
   ii. (HEALTH CANADA)
   iii. (EMA) - European Medicines Authority or a Western European country.
   iv. (SWISSMEDIC)
   v. (TGA) - Australian Medicines Administration.
   vi. (PMDA) - Japanese Ministry of Health.
   vii. (MHRA) - British Medicines and Health Products Authority.
4. the medicine or pharmaceutical products are marketed in the country of origin;
5. the manufacturing company must be registered with the NHRA manufacturers register or the Gulf Health Council;
6. the trade name, scientific name, strength, storage conditions, batch number, pharmaceutical form, production and expiry date, and the name and address of the manufacturer must be made available; and
7. imported batches must be transported and preserved in containers according to the conditions of transport and storage suggested by the manufacturer.

Upon the satisfaction of the abovementioned conditions, the NHRA requires the PPMH to append copies of the pharmaceutical product certificate ('CPP') and the good manufacturing practice ('GMP') certificate of the manufacturer prior to issuing an import permit. Furthermore, pharmaceutical agents in Bahrain are expected to comply with similar conditions for the importation of non-registered pharmaceutical products.

Version (1) of the Telemedicine Guidelines was issued in July 2020, thereby allowing telemedicine consultations to take place thorough licensed medical practitioners in Bahrain

Adopting NHRA-MVC traceability hub for pharmaceutical product traceability

In line with the NHRA's Medicines Barcoding and Serialization Guidelines, pharmaceutical manufacturers are now required to sign up to the NHRA-MVC Traceability Hub before January 2021 and obtain the adequate GS1 barcoding certificate no later than 1 October 2021 in order to comply with current importing standards. This landmark announcement places Bahrain on a par with the international community's pharmaceutical surveillance effort by emulating the policies and functions of the European Medicines Verification System. As such, all drug manufacturers and distributors must commit to attaching the Global Trade Item Number ('GTIN') on their packages in an attempt combat the trade of counterfeit pharmaceutical products in Bahrain.

Dispensing through the cloud

In 2020, the NHRA issued the first telemedicine licence in Bahrain to Doctori, a state-of-the-art telemedicine application aimed to serve a community at a time of distress. At the same time, it was announced that the NHRA would issue a guiding document aimed towards regulating drug-dispensing activity through mobile application.

Version (1) of the Telemedicine Guidelines was issued in July 2020, thereby allowing telemedicine consultations to take place thorough licensed medical practitioners in Bahrain. Substantial discretion has been given to Licensed Medical Practitioners ('LMP') in that if a medical condition requires a particular protocol to diagnose and prescribe, as in cases of in-person consultations, the same principle will be applicable to telemedicine consultations.

LMPs are thereby permitted to prescribe medicines via telemedicine if they are satisfied that they have adequate and relevant information about the patient's medical condition, and that prescribed medicines are in the best interests of the patient. Henceforth, prescribing medicines in the absence of a suitable diagnosis report will amount to professional misconduct.

The NHRA categorised a list of medicines that may be prescribed following a virtual consultation. These have been divided into three categories: List P, List POM, and the Prohibited List.

List P comprises medicines that are safe for prescription through any mode of tele-consultation. In essence, these include:

1. medicines that are used for common conditions and are often available as 'pharmacy only', i.e.: paracetamol, ORS solutions, and cough lozenges; and
2. medicines that may be deemed necessary during public health emergencies.

List POM (prescription only medicines): These medications may be prescribed during the initial video consultation and by follow-up prescriptions such as: clotrimazole, mupirocin, calamine lotion, benzyl benzoate lotion, local ophthalmological prescriptions and hypertension prescriptions.

Prohibited List: Namely, narcotic and psychotropic items.

Furthermore, any prescription issued via electronic mediums must contain all the relevant information appearing on the MOH's generic prescription sheet as well as containing the LMP stamp bearing his/her professional licence number.

Pharmaceutical manufacturers are now required to sign up to the NHRA-MVC Traceability Hub before January 2021 and obtain the adequate GS1 barcoding certificate no later than 1st October 2021.

Institutionalising the delivery of mental healthcare in Bahrain

On the margins of the virtual signing ceremony inducting Bahrain as an observer of the World Health Organization's Occupational Health Charter, the general secretary of the BMS informed media outlets that "in addition to the physical risks, the pandemic has exposed health workers to extraordinary levels of psychological pressure as a result of working extended hours in demanding conditions, and living in constant fear of exposure to the virus while separated from family."

With growing fears and apprehension towards the future of our mental wellbeing, NHRA introduced a governing framework aimed at institutionalising the treatment and delivery of mental care in Bahrain. This step entails embracing the importance of collective action aimed towards enhancing the current policy frameworks governing a key area of non-communicable diseases shrouded in taboo and gone astray. As such, Resolution 33 of 2020 extended a hand of support to the most vulnerable category of mental health patient – victims of addiction.

Applicants willing to obtain a commercial licence to run a rehabilitation facility are required to approbate their engineering sketches by the Healthcare Facilities Department – NHRA in addition to ensuring that day-to-day functions are supervised by a licensed medical consultant.

Furthermore, rehabilitation facilities are required to follow modern diagnostic methods implemented internationally through a qualified medical cadre. As such, Article 10 sets out the minimum medical qualifications to be held by each member; namely:

1. **Physician:** licensed by the NHRA, holding a fellowship in psychiatry, specialised training in addiction treatment for a period of at least two years;
2. **Psychology Specialist:** licensed by the NHRA, holding a bachelor's degree in clinical psychology in addition to six months training in addiction treatment or (alternatively) a master's degree in psychology;
3. **Clinical Nutrition Specialist:** licensed by the NHRA, holding a bachelor's degree in clinical nutrition;
4. **Occupational Therapy Specialist:** licensed by the NHRA, holding an accredited bachelor's degree in occupational therapy specialising in either mental health or psychology. A minimum of three years of practical experience is required;
5. **Physiotherapist:** licensed by the NHRA, holding an accredited bachelor's degree in physiotherapy; and
6. **Qualified Psychiatric Nurse:** licensed by the NHRA, holding a bachelor's degree in nursing and a higher diploma in nursing mental health, in addition to practical training for a period of no less than one year in the field of psychiatry.

Conclusion

The application of the PHL throughout COVID-19 tested the legislation, and demonstrated its flexibility and durability. The practical assessment of the PHL validated its success by corroborating the advantages of implementing harsh sanctions, as well as having flexible provisions to personalise each exposition reliant on it. The Kingdom of Bahrain is committed to the health and wellbeing of its citizens, and the government has adopted a modern trajectory by incorporating modern technology into everyday life with the chief aims of enhancing healthcare delivery, and the protection of potential new entrants into the local market.

For further information, please contact healthcare@tamimi.com.

Licensing pharmaceutical establishments in Jordan

Khaled Saqqaf
Partner, Head of Jordan & Iraq Corporate Structuring
k.saqqaf@tamimi.com

Thamer Shomar
Trainee Lawyer
Corporate Structuring
th.shomar@tamimi.com

The healthcare and pharmaceutical industries in Jordan have been a focal point economically considering the presence of several multi-national pharmaceutical companies that are based in the country. This required the Jordanian government to establish a robust legislation environment for companies to be well regulated in order to maximise quality assurance and reduce any fraudulent activity. The governmental authority responsible for regulating the said industries are the Jordanian Food and Drug Administration (the 'JFDA') and in turn the Ministry of Health (the 'MOH').

In recent years, Jordan has emerged as a key exporter of medicine and pharmaceuticals. This demanded the relevant authorities to revisit the basis for licensing the entities in the sector in order to establish a well organised regime for the same. The New Regulation for Licensing Pharmaceutical Establishments, No. 162 for the year 2019 ('New Regulation') came into effect once it was issued in the Official Gazette at the end of 2019.

The transportation, possession, distribution, sale, gifting, donation, purchasing, importing, and/or using pharmaceutical products and medication in Jordan is only permitted by companies holding a duly valid licence and registration from the MOH following approval of the Minister of Health. The said licence and approval can be granted to pharmaceutical manufacturers, pharmaceutical warehouses, pharmacies, and pharmaceutical research and development companies ('Pharmaceutical Establishments'). Additionally, it is not permitted to circulate or sell any medication or pharmaceutical products without registering the final form and obtaining an approval containing the permitted pricing of the same at the JFDA.

This article shall focus on highlighting the main requirements for registering a Pharmaceutical Establishment and obtaining an approval for the same from the competent authorities.

Pharmaceutical Establishment licensing

It is worth noting that an application to register a Pharmaceutical Establishment must be submitted by a person who possesses a university degree in pharmaceutical studies from an accredited university, and who is

registered as a pharmacist at the Jordanian Pharmacist Association ('JPA') and duly licensed to practise the profession pursuant to the Pharmacy and Pharmaceuticals Law (the 'Licensed Pharmacist'), with the exception of pharmaceutical manufacturers that have a separate licensing regime as outlined below.

Pursuant to the New Regulation, the Licensed Pharmacist must submit the application to the JFDA, with the following required documentation:

- documentation that proves the Licensed Pharmacist is readily available to supervise the Pharmaceutical Establishment;
- approval from the JPA;
- a copy of the Licensed Pharmacist's registration with the JPA;
- a copy of the national identification for the Licensed Pharmacist;
- a land deed or lease agreement for the property to be used for the Pharmaceutical Establishment;
- initial approval of the Greater Amman Municipality, or any other relevant Municipality for the registration of the Pharmaceutical Entity on the said property;
- a certificate for the trade name of the Pharmaceutical Entity in the name of the Licensed Pharmacist; and
- an undertaking to abide by all issued regulations and instructions relating to the technical, health, equipment, and any other relevant specifications that the Pharmaceutical Establishment must have.

In recent years, Jordan has emerged as a key exporter in relation to medicine and pharmaceuticals. This demanded the relevant authorities to revisit the basis for licensing the entities in the sector in order to establish a well organised regime for the same.

Once the application and required documentation have been submitted, a committee shall conduct an examination of the property wherein the Pharmaceutical Establishment shall be located to ensure all regulations and instructions relating to the same are met.

The MOH shall obtain the following licensing fees for Pharmaceutical Establishments:

- JOD 2,000 (approximately US$4,000) for private pharmacies;
- JOD 1,000 (approximately US$1,400) for a pharmaceutical warehouse;
- JOD 1,500 (approximately US$2,000) for a pharmaceutical research and development company; and
- JOD 1,500 (approximately US$2,000) for a pharmaceutical laboratory.

Pharmaceutical manufacturers licensing

Pharmaceutical manufacturers are treated differently and have a separate licensing regime to the remaining Pharmaceutical Establishments. The application for registering a pharmaceutical manufacturer must be submitted to the JFDA with the following required documentation:

- a land deed or lease agreement for the property to be used for the pharmaceutical manufacturer;
- a regulatory site plan of the property;
- the company's certificate of incorporation; and
- initial approval of the Greater Amman Municipality, or any other relevant Municipality for the registration of the pharmaceutical manufacturer on the said property;

The JFDA shall review the application to ensure all requirements have been met and then conduct an examination of the property wherein the pharmaceutical manufacturer shall be located to ensure all regulations and instructions are satisfied. The committee shall then submit the documentation and the report of the examination to the Director of the JFDA within 14 working days. The Director of the JFDA then submits the documentation and a recommendation to the Minister of Health to provide the final decision within 30 working days from the date of examination.

It is worth noting that the approval to establish a pharmaceutical manufacturer shall be deemed nullified if the said pharmaceutical manufacturer has not been established within three years of obtaining the approval.

The MOH shall obtain the following licensing fees for pharmaceutical manufacturer:

- JOD 500 (approximately US$700) upon submitting the application for establishing a pharmaceutical manufacturer;
- JOD 4,000 (approximately US$6,000) upon granting the licence; and
- JOD 1,000 (approximately US$1,500) upon licensing any additions to the factory.

Pharmaceutical Establishment termination

The licence for a Pharmaceutical Establishment may be terminated by a decision by the Minister of Health in the following cases (amongst others):

- if the Pharmaceutical Establishment does not commence commercial activities within one year of obtaining the licence, except pharmaceutical manufacturers who have three years as mentioned above;
- if the Pharmaceutical Establishment closes for a continued period of six months without just cause;
- if the Pharmaceutical Establishment does not abide by the relevant instructions and regulations; and/or
- if the licence has been granted based on fraudulent documentation or incorrect information.

The Pharmacy and Pharmaceuticals Law also stipulates several penalties and fines, in addition to the termination of the licence.

Conclusion

In conclusion, Pharmaceutical Establishments, including Pharmaceutical Manufacturers, are heavily regulated in order to advance the industry and improve the production, storage, and retail of pharmaceutical products in Jordan. Additionally, notwithstanding the regulations relating to licensing Pharmaceutical Establishments, the JFDA enforces international standards in relation to the raw materials used in pharmaceuticals and the overall quality of the same in order to compete on a global scale, and in order to ensure Pharmaceutical Establishments abide by the said regulations, the JFDA has the authority to conduct scheduled inspections and issue penalties accordingly in the case of breaches.

For further information, please contact healthcare@tamimi.com.

Distributing herbal medicine and teas in Kuwait

Lulwa Al Hammad
Associate
Corporate Commercial
l.alhammad@tamimi.com

Kuwait's Pharmaceutical and Herbal Medicines Registration and Control Admission at the Ministry of Health ('MOH') issued a Ministerial Decree this past July for the registration of herbal medicines and herbal preparations No.101 for the year 2020 ('Decree 101/2020').

Previously, Kuwait lacked a classification system for herbal medicines, relying mainly on the classification of the product in the country of origin, which led to many herbal medicines being classified as dietary supplements and thereby escaping rigorous assessment. The classifications and definitions put into place under Decree 101/2020 provide a clearer pathway for determining the level of regulatory control that is most appropriate for evaluating quality, safety and efficacy.

Decree 101/2020 addresses the following:

1. local agent, market authorisation holder ('MAH'), and manufacturing company registration requirements;
2. herbal products and herbal teas classification and registration requirements; and
3. variations, transfer of agency, suspension and cancellation of an herbal product/herbal tea registrations.

In this article, we address a number of key issues:

1. Local agent, MAH, and manufacturing company registration requirements

In line with the relevant regulations of the State of Kuwait, pharmaceutical products, including herbal products and teas, may only be brought into the local market via a local appropriately licensed agent and following registration with the Kuwait Drug and Food Control and Administration ('KDFC') at the MOH. The burden of such registration requirements rests with the local licensed agent.

Both the locally licensed agent as well as the MAH (defined under Decree 101/2020 as the pharmaceutical company that legally holds the right and responsibility of marketing the product in Kuwait) must be registered with the MOH. If the manufacturer is different to

the MAH, then the manufacturing site will also need to be separately registered with the MOH.

A non-exhaustive list of documents required for a new agent to register with the MOH is as follows:

1. copy of valid licence from the Ministry of Commerce and Industry, which includes the activity of "sales of medicine";
2. copy of valid store licence issued by the Drug Inspection Authority; and
3. copy of authorised personal signatures.

When registering a MAH, documents to be submitted would include, but are not limited to the following:

1. legalised letter of appointment ('LOA') from the MAH stating that the local agent is the sole and/or exclusive agent in the State of Kuwait;
2. original legalised manufacturing licenses from the country of origin for each manufacturing site, issued by the MOH or concerned regulatory authority in the country of origin;
3. original legalised Good Manufacturing Practice Certificate from the country of origin;
4. list of herbal products/teas manufactured by the company; and
5. site master file, for herbal products other than herbal teas.

2. Herbal products and teas

As per Decree 101/2020, an herbal product is defined as "any medicinal product, exclusively containing active ingredients consisting of one or more herbal substances or herbal preparations or such herbal substances, in combination with such herbal preparations that are intended for prophylactic, therapeutic, or other human health benefits". Herbal teas are also considered herbal products, with the distinction being that they are "packed into paper or cloth bags or sachets, each containing ground herbal materials sufficient for one dose for making an infusion . . . [and] . . . including a clear medical / therapeutic indication explaining its purpose".

Herbal products and herbal teas must be registered with the Kuwait Drug and Food Control and Administration.

Herbal products, excluding herbal teas, are classified as either herbal medicine ('HM') or traditional herbal medicine ('THM'). HM can be seen as products that have been tried and tested, the efficacy of which has been demonstrated via clinical data whereas, THM relates more to the knowledge, skills, and theories native to different cultures, such as Ayurvedic Medicine, which in contrast is not supported by traditional clinical evidence. Applications for HM registrations are required to be supported by scientific references supporting the pharmacological claims and a study showing the pharmacological action of the product, amongst others. On the other hand, THM registration applications are required to demonstrate that the product has had a period of at least 30 consecutive years of traditional use.

Amongst other requirements, applications for the registration of herbal teas are required to be submitted with a certificate of analysis of the finished product, which must include total ash, acid, insoluble ash, moisture content at 110 °C, microbiology and, in the case of fresh herbal substances, heavy metals. Further, safety and efficacy studies from competent international authorities (and/or evidence of tradition use or clinical studies, in line with those required for HM and THM herbal medicines) must be submitted.

The registration for herbal products, including herbal teas, must be renewed every five years.

3. Variation, transfer of agency, suspension and cancellation of an herbal product/herbal tea

It is important to keep the MOH informed of any changes to the agency relationship and the product, whether it be a transfer of an agency, cancellation of a product's registration, or changes/additions made to the registered product. In each case, the MOH's approval must be obtained of such changes or additions.

Should the MAH opt to operate in Kuwait via a different agent, then a legalised LOA for the new local agent issued from the MAH, termination letter issued from the MAH specifying the date of termination of the local agent, and list of products affected by the transfer must be submitted.

The MOH has the discretion to cancel the registration of herbal products or teas for non-compliance with Decree 101/2020 and in certain other situations, such as: (i) the herbal product or tea is banned or suspended in the country of origin or any other country for safety reasons; (ii) documents submitted are false; or (iii) two years have passed without the registered product having been imported.

Both the local agent and the MAH should ensure compliance with local law requirements, specifically with respect to banned ingredients. Such ingredients are annexed in Decree 101/2020 under two main umbrellas: (i) narcotic and poisonous herbs, which cannot be included in herbal products or tea submitted for registration; and (ii) herbal ingredients subject to specific restrictions (i.e. acceptable limits). In addition, the MOH has the right to restrict any herb or plant that is proven harmful for human use.

4. Additional considerations

The local agent, MAH, and manufacturer should also take into account the requirements set forth under Law No. 13 regulating Commercial Agencies in Kuwait ('Agency Law') and Law No. 68 of 1980 promulgating the Commercial Law (the 'Commercial Law'), alongside the health regulatory considerations specified above.

Aspects such as exclusivity versus non-exclusivity, agency registration requirements, and governing law and dispute resolution clauses are paramount when drafting commercial agency agreements (such as distribution agreements) and must be analysed based on the specific case at hand. For instance, the Commercial Law allows the principal (such as the MAH) to utilise the services of more than one agent or distributor in the same area and for the same branch of activity. Similarly, the Agency Law provides that the principal may have more than one agent or distributor. Yet these are contrary to Decree 101/2020 and various other health regulations which require a LOA stipulating that the local agent is the sole, exclusive agent for the pharmaceutical product and/or herbal products or tea.

Parties should not turn a blind eye to engaging in a legal review prior to execution of their distribution agreements in order to minimise the risks of disputes ending up in court battles and subjecting the foreign principal to local laws that were perhaps not originally contemplated in the drafting of the distribution agreement.

For further information, please contact healthcare@tamimi.com.

Oman's new executive regulations to the pharmacy laws

Arif Mawany
Senior Associate
Corporate Commercial
a.mawany@tamimi.com

Overview

The Ministry of Health of Oman ('Ministry') recently passed Ministerial Resolution number 113 of 2020, issuing the executive regulations of the law regulating the practice of the pharmacy profession and pharmaceutical establishments ('Regulations'). The Regulations are a progressive step forward and codify the registration and licensing regime of medicinal drugs and pharmaceutical businesses in Oman, in addition to clarifying the process of establishing pharmaceutical research centres and pharmaceutical consultancies. The Regulations expressly repeal the Ministry of Health resolution numbers 73 of 2000, 74 of 2000, 84 of 2000, 86 of 2000 and 2 of 2001.

Registration of medicinal drugs

The Regulations clarify that, before any medicinal drug can be distributed to the public in Oman, the drug must first be registered with the Ministry. This registration requirement applies whether the drug has been locally manufactured or imported. Registration entails a process that involves providing documentation that confirms that the drug has been registered and is marketed in the country of origin and with the same chemical composition. Whether a drug is subsequently approved for registration depends ultimately on both its 'therapeutic' significance and the standards laid down by the Ministry. Upon registration, the Regulations stipulate that the Ministry will list the drugs that have been submitted for registration on its website, which coincides with the practice currently followed by the Ministry. Registration is valid for five years and can be renewed for subsequent periods. No changes may be made to the price, chemical composition, specifications, or manufacturing method of the registered drug without prior consent from the Ministry.

It is important to note that the Regulations expressly stipulate that the Ministry will collect samples of registered drugs at regular intervals to verify that they continue to comply with technical specifications that were submitted at the time of registration. The Ministry will step in to suspend and recall a registered medicinal drug in the following circumstances:

1. the drug is proven to be harmful or toxic or has shown to give rise to serious side effects;
2. registration of the drug in the country of origin has been revoked or production has been prohibited or limited in the country of origin;
3. changes have been made to the components of the medicinal drug, specifications, manufacturing, or marketing methods without receiving prior approval from the Ministry; or
4. the medicinal drug no longer fulfils any of the conditions that applied at the time of registration.

Registration and licensing of entities in the pharmaceutical sector

The Regulations provide clarity on the different establishments that may be formed for the purpose of selling and storing medicinal products, conducting research and scientific study in the pharmaceutical sector, and the provision of consultancy type services in connection with increasing awareness in the pharmaceutical sector. The different establishments available under the Regulations, along with a brief overview of the respective licensing requirements, are described below.

Registration to distribute medicinal drugs or medical devices can be undertaken by utilising the services of a local distributor or authorised representative. In other circumstances, registration and licensing with the Ministry of Commerce, Industry and Investment Promotion (previously, the Ministry of Commerce and Industry) will be a prerequisite to registration...

Pharmaceutical companies

Foreign companies that develop and manufacture medicinal drugs or herbal medicines are permitted to register those drugs in Oman. Registration enables their medicinal drugs or herbal medicines to be distributed into the Omani market by a locally appointed distributor. The key requirements (not an exhaustive list) for a pharmaceutical company to register with the Ministry are as follows:

1. the pharmaceutical company must hold licences to operate one or more factories and be able to show that it is registered in at least three countries (which such registration the Ministry may possibly interpret as a licence to distribute those drugs in three different countries);
2. it holds a certificate of good manufacturing practice from its country of origin;
3. medicinal drugs manufactured by the company are distributed in its country of origin with the same specifications, composition, manufacturing, and analysis methods as are proposed to be distributed in Oman. The company will be asked to provide a written undertaking to the Ministry to confirm this position;
4. details of the organisation of the company must be provided including divisions, number of employees, and educational qualifications within the production, quality control, and R&D departments;
5. certificates confirming innovative discoveries during the previous ten years; and
6. details of the pharmaceutical company's distributor or representative in Oman.

Once approval has been given to a pharmaceutical company to register its medicinal drugs for distribution, a licence is issued for five years, renewable. It is pertinent to note that once registered, if the pharmaceutical company undergoes a sale or merger, or acquires another pharmaceutical company, written notice must be provided to the Ministry within 90 days following closing of the applicable transaction.

Herbal medicine companies

Companies that manufacture herbal medicines, which are broadly defined under the Regulations as substances of plant origin that are used for disease prevention or treatment, may register with the Ministry provided that they are able to fulfil a number of conditions, as stipulated in the Regulations. Those conditions are the same as those for registration of mainstream pharmaceutical companies, with the addition of the following specific conditions:

1. the company has a certificate of good agricultural practice issued by authorities in that company's country of origin;
2. detailed information on the raw materials used in the composition of the medicine;
3. written evidence from the health authorities in the country of origin stating that the medicines are free from steroids, sex hormones, aflatoxin, pesticides and pest, rodent, or animal debris; and
4. written evidence from health authorities in the country of origin confirming that the medicines are free from any chemical substances.

Pharmacies

The Regulations now clarify the process required to licence a pharmaceutical establishment. The Regulations indicate that the process of documentary registration is a straightforward procedure with detailed provisions focusing on the health and safety of the premises, materials used to construct the pharmacy, and controlling the temperature of medicines. It should be noted that pharmacies are classified as either 'public', namely those that are open to the public at large, or 'private', which are enterprises that hold a licence to service the patients of private hospitals. Various conditions stipulated in the Regulations must be fulfilled before a public pharmacy is issued a licence, including assessing the maximum distance from the nearest health facility and minimum distance from other public pharmacies in that vicinity. Private pharmacies are subject to fewer conditions given that they are generally in existence for the purpose of serving the patients of private hospitals. The key condition for private pharmacies is that they must be located within a private hospital and have a total internal area of no less than twenty square metres.

Pharmaceutical warehouses

The Regulations now expressly regulate the licensing of warehouses that have been established to sell medicinal drugs to government health institutions in Oman, other pharmaceutical warehouses, and other entities approved by the Ministry. These warehouses are not permitted to sell medicinal drugs to the public or to offer samples. The structure, size and internal conditions of the pharmaceutical warehouse are all strictly controlled under the Regulations, but are likely to be fairly easily satisfied by most commercial premises in Oman. Before a licence can be issued to operate from the warehouse, the owner of the warehouse must adduce evidence that it has entered into an arrangement under which a specialist service provider will remove and dispose of all damaged and expired medicinal drugs.

The Regulations are a progressive step forward in codifying the registration and licensing regime of medicinal drugs and pharmaceutical businesses in Oman, as well as providing clarity on the process of establishing pharmaceutical research centres and pharmaceutical consultancies.

Scientific offices

Scientific offices are classified as establishments that contribute to scientific studies and research in co-operation with scientific centres in Oman. Such offices serve other purposes, such as raising health awareness, contributing to vocational learning programmes, and supporting various scientific activities. Obtaining a licence to establish a scientific office requires a full time pharmacist who will act as manager of the office, but who is not permitted to sell medicinal drugs or offer free samples to the public. Before a licence can be issued, it must be shown that the scientific office is not part of any other pharmaceutical establishment.

Pharmaceutical consulting firms and pharmaceutical research centres

Pharmaceutical firms, particularly those based outside Oman, may have a desire to provide consultation, research, or studies in connection with pharmacy practice and improve awareness through the organisation of scientific events. In such circumstances, a licence to operate a consulting firm is required. Licensing requirements are minimal but it is important to be aware that the manager of the firm must be a full time pharmacist of Omani nationality.

The Regulations outline the purpose of pharmaceutical research centres of carrying out clinical research and medical analysis on volunteers for the purpose of ascertaining the stability of medicinal drugs. A pharmaceutical research centre is capable of being established and licensed in Oman provided it meets certain criteria, the key one being that the centre must satisfy global clinical GMP and laboratory GMP standards.

Medical supply companies

A separate and distinct classification under the Regulations relates to companies that wish to import medical devices into Oman. Those companies are subject to a controlled registration process that involves providing evidence of quality management and regular technical inspections in the country of origin. Although registration of the medical device is usually a condition of importation into Oman, the Regulations grant the Ministry the power to approve the importation of unregistered medical supplies in exceptional situations and subject to rules that are due to be published in the future. Products that are found to be unsafe or that have been altered after the registration process has been completed and without the Ministry's consent will have their registration revoked.

In all cases, advertising of and promotional literature for registered medical supplies may not be distributed in Oman without the prior approval of the Ministry.

Conclusion

The Regulations are a helpful, single point description of the licensing regime for the various entities that are capable of registration under Omani healthcare law. In circumstances where a foreign pharmaceutical business may be looking to ascertain the viability of formally establishing itself in Oman, it will be able to make use of the various entities available under the Regulations all of which are considered different components within the mainstream pharmaceutical sector. Registration to distribute medicinal drugs or medical devices can be undertaken by utilising the services of a local distributor or authorised representative. In other circumstances, registration and licensing with the Ministry of Commerce, Industry and Investment Promotion (previously, the Ministry of Commerce and Industry) will be a prerequisite to the registration of a pharmacy, pharmaceutical warehouse, scientific office, or pharmaceutical consulting firm with the Ministry of Health.

For further information, please contact healthcare@tamimi.com.

Contact tracing application made compulsory in Qatar

Frank Lucente
Partner
Corporate Commercial
f.lucente@tamimi.com

Nuša Gorenjak
Trainee Lawyer
Corporate Commercial
n.gorenjak@tamimi.com

Qatar has introduced a compulsory contact tracing application called 'Ehteraz' as part of its measures to combat the COVID-19 pandemic. The name 'Ehteraz', which is Arabic for 'precaution', makes it clear that the application has been introduced as an additional precautionary measure to prevent the spread of the virus by identifying transmission chains and allowing contact tracing. However, the application has additional helpful features such as informing users on the latest developments and official statistics regarding COVID-19 and allowing users to receive awareness and precautionary instructions from the health authorities. As such, if users have been in contact with an infected person or a person in quarantine, they will receive an on-the-spot notification through the application.

Ehteraz is compatible with Android and iOS systems (although there have been some issues with older telephones) and uses GPS location and bluetooth to trace the individual's location. Therefore, users need to have both location and bluetooth settings turned on at all times in order for Ehetraz to work properly.

At first, Ehteraz was available only for users who had a Qatar Residence Permit. However, with later updates the application was made available for users on visit and business visas also.

The main feature of the Ehteraz application is that a profile of each user is linked to a QR code by automatically extracting the user's health information gathered by official authorities and categorising users in the following groups:

- **Red –** for people who have tested positive for COVID-19 and remain so;
- **Yellow –** for individuals who are in quarantine facilities;
- **Grey –** suspected cases, individuals who exhibit symptoms or who have been in contact with COVID-19 positive cases but have not been tested; and
- **Green –** healthy individuals who do not exhibit any COVID-19 symptoms or who have tested negative.

Qatar has introduced a compulsory contact tracing application called "Ehteraz" as part of its measures to combat the COVID-19 pandemic.

If an individual is suspected by the health authorities to be infected, the status on Ehteraz changes to grey however, from the moment that the COVID-19 test is done the status changes to yellow and it remains yellow until results are known. This would occur in situations where a close family member has a red status or there are other circumstances where there is a high degree of possibility of close exposure to an infected person. In the interim, individuals must quarantine themselves and are not allowed to enter any public places. If the results of the test are positive, the status changes to red, and if the results are negative the status changes back to green.

In cases where an individual's status is red, the application allows the checking/tracing of an individual's movements from the time that the application was downloaded until the moment of infection. From such location information, health authorities can also identify individuals who were in contact with the individual who tested positive. Such individuals would receive the notification through Ehteraz of potential infection and would have priority in receiving testing services and results. This is all designed to facilitate a quick reaction to situations and to alleviate the risk of such infected individuals spreading the virus.

Compulsory

Initially, residents were only encouraged to use the application, but as the number of positive cases increased, the government made the application mandatory for all residents when leaving their homes. Consequently, the vast majority of public places, such as stores, banks, public institutions, and workplaces have decided to make a "green" health status on the Ehteraz a mandatory prerequisite to entry.

Legal basis

In March 2020, Qatar promulgated Law no. 9 of 2020 amending provisions of Law no. 17 of 1990 on the Prevention of Infectious Diseases (together 'Law on the Prevention of Infectious Diseases'). Based on the said law, Qatar authorities are permitted to implement general procedures and measures for public health, including imposing restrictions on the individual's freedom to gather, move, and remain in specific places or at specific times in order to limit the spread of infectious diseases. Moreover, the Law on the Prevention of Infectious Diseases imposes reporting requirements on employers, doctors etc. to report a person suspected of having a contagious disease.

The Law on the Prevention of Infectious Diseases provides the legal basis for the government to impose such measures that it deems necessary, including the obligatory use of Ehteraz, mandatory wearing of face masks, and temperature checks in order to protect the public health. Furthermore, penalties for non-compliance are severe with possible imprisonment for a period not exceeding three years and/or a fine not exceeding QAR 200,000 (US$54,945.05).

Is Ehteraz an effective measure to combat the spread of COVID-19 ?

When Qatar introduced the mandatory use of Ehteraz, there were some reservations on the part of the public as to whether such an application would be effective in combating the spread of the virus and whether it is too invasive to the individual's personal life. There were also concerns in connection with personal data that the government would collect with implementing the mandatory use of Ehteraz.

Qatar has a specific data protection law being Law no. 13 of 2016 (the 'Data Protection Law') that regulates an individual's personal data and poses obligations on data controllers and data processors.

In general, personal data should not be processed without an individual's consent, unless there is a legitimate purpose for such processing. Furthermore, any health-related data is considered as sensitive personal data, and due to its sensitivity a special permit from the relevant department at the Ministry of Transport and Communications along with the data subject's consent needs to be obtained prior to such processing.

However, the Data Protection Law provides for an exception from complying with the above mentioned processing requirements, if such processing is necessary to protect the public and provide security. Accordingly, the data collected by the Ehteraz application is justifiable under the law on the basis of being in the interests of public safety and, as such, the data collected from users for the purpose of tracing the users' location in cases of an infection from a communicable disease would not be a legal issue.

For further information, please contact healthcare@tamimi.com.

KSA: Vision 2030 update in relation to healthcare

Julie Bassi
Senior Associate
Corporate Commercial
j.bassi@tamimi.com

Somaia Bugis
Trainee Lawyer
Corporate Commercial
s.bugis@tamimi.com

Way back on 25 April 2016 Saudi Arabia unveiled Vision 2030, a plan of action to transform its economy through the development and creation of alternative sources of income for the Kingdom. On the back of this, the National Transformation Program 2020 ('NTP') was announced in June that year as an interim measure for laying the foundations to achieve the aim of Vision 2030.

Healthcare was one of the growth areas identified in Vision 2030, with the aim of developing the private sector and reducing the reliance on the public health system. The NTP established a set of national priorities and goals to be achieved through job creation, strengthening partnerships in the private sector, maximising domestic industries, and digital transformation.

The NTP established strategic objectives for the Ministry of Health ('MOH'), the Saudi Food & Drug Authority ('SFDA'), and the Ministry of Investment ('MISA'), which included attracting foreign investment, improving the efficiency of the healthcare sector, nurturing private-public partnerships, and increasing the use of information technology and digitalisation.

Vision 2030 is an ambitious plan and is still ten years' away before it reaches fruition. This article explores what has been achieved so far and the developments made to date. (Our original post on the topic, entitled Vision 2030 and the Opportunities it Represents in Healthcare in Saudi Arabia, can be found here.

Digital innovations and e-prescriptions

One of the objectives of the MOH was the implementation of electronic medical records in all healthcare institutions (within both the private and public sectors) with the eventual aim of a Unified Medical Record System ('UMRS'), which will enable institutions and the MOH to share information. We understand that all MOH healthcare institutions and the majority of private healthcare institutions utilise electronic medical records for their patients. However, the UMRS is yet to be implemented.

All MOH healthcare institutions now communicate with their patients through sending notification of their upcoming appointments and their medical prescriptions (by virtue of their national identity number) to their mobile phones.

All MOH healthcare institutions now communicate with their patients by sending notifications of their upcoming appointments and their medical prescriptions (by virtue of their national identity number) to their mobile phones. This enables patients to confirm or cancel appointments through this medium and arrange to collect prescriptions from designated pharmacies. Many hospitals in the private sector have a similar system for notifying patients of pending appointments, in addition to having access to online appointments and access to medical records.

E-prescriptions are now possible in Saudi Arabia and pharmacies within the Kingdom can now apply to the MOH to implement an electronic system for providing e-prescriptions. All pharmacies in Saudi Arabia must be Saudi owned in accordance with Saudi Law and foreign ownership is not permitted therefore, only Saudi nationals are able to fulfil an order for e-prescriptions. However, it is possible for foreigners to implement an online e-prescription service that is fulfilled by a Saudi owned pharmacy with which it is partnered.

Both the MOH and the SFDA provide online services and it is possible for registrations and applications to be made via this platform. Furthermore, all correspondence with both agencies must initially be made online (or through a call centre for the MOH) before matters can be dealt with physically. The SFDA has online databases available to users relating to pharmaceuticals and medical devices (in addition to food and animal feed). All initial applications for investment licences are made online to MISA through their online portal and queries are dealt with through a call centre and online.

Telemedicine and teleconsulting

Telemedicine and teleconsulting (collectively 'Telemedicine') is now a regulated activity in Saudi Arabia. Previously, it was a tolerated practice before a licensing regime was introduced in December 2018 and Telemedicine Regulations ('Regulations') were published in June 2019. The Regulations state that telemedicine is available for screening, triage, consultation, diagnostics, obtaining a medical opinion from a healthcare practitioner, treatment support, and the monitoring of a medical condition. Telemedicine can be practised by foreign investors in the Kingdom and all legal requirements and protocols that are applied to healthcare practitioners in physical practice in Saudi Arabia equally apply to the practice of telemedicine.

The MOH, through its public health services section, now provides telemedicine services through patients calling a designated telephone number (937) to obtain an initial medical consultation, and there is no need for an appointment to utilise this service and seek medical consultation. If the patient's health query can be resolved and if medication is required, the MOH will send a text message to the patient with a prescription number to get free medication from designated pharmacies. If further investigation or treatment is required after the initial consultation, patients can book appointments through the Sehha application, which then informs the patient of the nearest healthcare institution (public) to attend the required appointment. A number of private healthcare centres now provide a telemedicine service to complement their physical healthcare service, and in some cases this is a partnership with an overseas, high profile healthcare provider.

Foreign investment and ownership

Previously, foreigners could only own and manage hospitals and were unable to own or manage other healthcare institutions (such as clinics and laboratories). However, the Private Healthcare Institutions Law 3/11/1423H was amended in early 2019

All MOH healthcare institutions now communicate with their patients through sending notification of their upcoming appointments and their medical prescriptions (by virtue of their national identity number) to their mobile phones.

and now foreigners can own or manage (with appropriate qualified personnel) all healthcare institutions with the exception of clinics (ownership of polyclinics or specialised polyclinics is permitted) and the MOH and MISA will now issue the relevant licences. Pharmaceuticals and medical devices still can only be distributed through Saudi own and based distributors if such products are not manufactured in the Kingdom.

As one of the goals of Vision 2030 is to improve the quality of healthcare services and promote competition amongst healthcare providers, the ability of foreigners to own or manage healthcare institutions paves the way for foreign investment by making it more attractive for the right investors to invest their expertise, capabilities, energy, and finances in the Kingdom. This development clearly demonstrates the Kingdom's commitment to meeting the goals of Vision 2030 relating to increased competition and a more efficient healthcare system.

Private healthcare insurance

Private healthcare insurance is now compulsory for expatriates and Saudi nationals (and their dependents) working within the private sector. There also appears to be a move towards the healthcare needs of public sector employees being provided through private healthcare insurance. It was recently announced that four government ministries have entered into or are in the process of entering into arrangements with specialised companies to provide medical insurance services for their employees (Ministry of Finance, Ministry of Commerce, Ministry of Tourism, and Ministry of Economy & Planning). It is only a matter of time before other government ministries and agencies follow suit in order to reduce the burden on the public health system.

The Implementing Regulations of the Co-operative Health Insurance Law 8/05/1430H were recently amended to state that private healthcare insurers must provide

coverage within their insurance provision for telemedicine services, which is a clear indication of how important this method of providing healthcare now is within the Kingdom. The use of remote consultation will increase, and this is especially so following on from the COVID-19 pandemic.

The Kingdom's response to the COVID-19 pandemic

One of the objectives of the MOH within Vision 2030 was to adopt a national plan for emergency response to public threats in line with international standards, and Saudi Arabia's response to the COVID- 19 pandemic has surpassed the efforts of many countries. The MOH has developed several online applications to track the spread of COVID-19 and to ensure essential healthcare services are provided to citizens, residents, and visitors currently in the Kingdom. The online applications are as follows:

- the Tetamman Application is designed to provide services for those who have been in contact with an infected person, have COVID-19 symptoms, citizens and residents who have arrived back in Saudi Arabia from abroad, and infected cases who have been referred to isolation and/ or quarantine period;
- the Tabaud Application alerts whoever downloads Tabaud when they have come into contact with an infected person. For the application to be effective, Bluetooth is required and this application is linked with the Tawakkalna application;
- the Tawakkalna Application has predominantly been used during the lockdown period that took place around May and June this year. During curfew hours, citizens and residents had to obtain approval to leave their houses through this application. Since the end of lockdown, Tawakkalna is now used to obtain Umrah permits and book COVID-19 tests, amongst other services.

The MOH now provides telemedicine services through patients calling a designated telephone number (937) to obtain an initial medical consultation and there is no need for an appointment to utilise this service and seek medical consultation.

Currently, all medical treatment that relates to COVID-19 is provided free of charge to all citizens, residents, and visitors in the Kingdom in an effort to curb the spread of the virus. Furthermore, the MOH provides COVID-19 PCR tests free of charge at various locations throughout the country, with all results being made available the same day. This is to ensure infected cases are identified quickly and all necessary action can be undertaken.

Conclusion

Great strides have been made within healthcare, especially with digitalisation and the provision of online content. The MOH, SFDA, and MISA are now working much more efficiently than pre-Vision 2030 and approvals and the issuing of licenses are being issued within record time. The healthcare offering both with the private and public sector has vastly improved and service levels are much higher with patients being the beneficiaries of such changes. We are now seeing foreign investor interest in the provision of an expanded scope of healthcare treatments and we are likely to see more foreign investment in healthcare centres, in particular.

The Kingdom has shown itself to be a world leader in its response to the COVID-19 pandemic and this can be demonstrated through the ever decreasing number of infections despite the fact that most of the world is heading towards or is experiencing a second wave of infections. The healthcare objectives of Vision 2030 are well on their way to being achieved on target and Saudi Arabia can look to the future with confidence in this growth area.

For further information, please contact healthcare@tamimi.com.

E-commerce and online pharmacy/ beauty stores in the UAE: Questions of licences and locations

Omer Khan
Partner
Corporate Structuring
o.khan@tamimi.com

Nazanin Maghsoudlou
Senior Associate
Corporate Structuring
n.maghsoudlou@tamimi.com

Moving from traditional to online pharmacy in the UAE

E-commerce and online pharmacy

In 2020, most potential customers have access to a smart phone or a personal computer laptop through which they can buy products and services. Market researchers anticipate an annual increase in sales of 20 per cent over the next five years, and suggest that gross revenues from online pharmacy will exceed US$131 billion in 2025. The drivers of the expansion include increased per capita incomes in emerging markets, greater self-medication by patients and aggressive sales promotions by manufacturers and distributors.[1] The COVID-19 pandemic may have provided an additional boost, given that it encourages people to shop online rather than at traditional shops.

Hence, online pharmacy is a large commercial opportunity, both in the United Arab Emirates ('UAE') and globally. This is partly because of the huge variety of products that are typically offered by both traditional 'bricks and mortar' and online pharmacies. Customers may buy prescription medicines, over-the-counter medicines, alternative medicines, cosmetics, beauty and personal care products and often much else.

All this begs the question: what are the official licences that are needed to offer products via an online pharmacy or beauty stores to customers in the UAE?

Relevant regime in the UAE

Registered pharmacy or beauty store players

For a traditional pharmacy or chain of pharmacies that are already registered in mainland UAE, the move into online business is a relatively straightforward process. This is on the basis that they are already subject to the rules and requirements of two regulatory bodies. One is the Ministry of Health and Prevention ('MOHAP') and/ or healthcare regulator of the Emirate in

[1] *https://www.finanzen.at/nachrichten/aktien/worldwide-online-pharmacy-industry-to-2025-increase-in-health-awareness-&-demand-for-self-medication-presents-opportunities-1029641825*

the nature of licences or approvals … will depend on whether the online sale is being contemplated by an already registered pharmacy … in the UAE or through third-party e-commerce aggregators.

question (e.g. Abu Dhabi's Department of Health or the Dubai Health Authority). The other is the relevant body that has issued the company's commercial trade licence (e.g. the Department of Economic Development in Abu Dhabi or Dubai).

In addition to the above mentioned licenses, an established pharmacy (or chain) that wishes to move into online pharmacy needs to apply to DHA for tele-pharmacy services.

To obtain the required commercial licence it may be necessary to also obtain a no objection letter ('NOC') from the Telecommunications Regulatory Authority ('TRA') to declare that the TRA has no concerns about the e-commerce activity. Such a NOC can be applied for online from the TRA however, the exact status of the NOC and when it is needed is not completely clear.

As an alternative to setting up its own online presence, an established pharmacy or beauty store may choose to distribute through an established e-commerce aggregator. This is explained below in terms of what licenses and approvals would be required.

Third party aggregator e-commerce platform players

A third party e-commerce aggregator platform or website can create a marketplace for the sale of healthcare and beauty products online, but the key issue is that the pharmacies or beauty stores that participate in the marketplace for supplying the products are properly licensed by the relevant health regulators in the UAE. In this case, assuming that the participant pharmacies are already registered with DHA for tele-pharmacy services, the e-commerce aggregator itself will not require a licence from the relevant healthcare regulator and would only need to apply for a commercial trade licence from the relevant Department of Economic Development of the emirate in question or from a free zone authority.

The aggregator may also need to obtain a NOC from the TRA for selling products online. Further, if the e-commerce aggregator is creating a marketplace for the sale of products of third party pharmacies and beauty stores in the UAE, it will likely also need to apply to the National Media Council ('NMC') for an e-media permit. The remit of the NMC under the 2018 Electronic Media Regulation Resolution (the 'E-Media Law') is broad and vague, but includes the licensing of "specialised websites (e-ads, news sites, … etc.)". Anecdotally, we know this to mean the provision of services aligned with 'classified advertising', whereby a publisher or platform takes money from a third party to include their products in their listings.

In both instances of registered pharmacies or beauty stores and a third party e-commerce aggregator, the website owners or administrators must ensure that their websites comply with all federal and local regulations related to health advertisement and advertising on social media as well as the internet access guidelines in the UAE in order to avoid regulatory breaches and potential blocking of a page or the platform itself.

Market researchers anticipate an annual increase in online sales of 20 per cent over the next five years

Jurisdictional choices

The e-commerce aggregator will have the option of setting up a presence either 'onshore'[2] or in one of the available 'free zones' that have been established throughout the UAE and would not be subject to the mainland trading restrictions that the free zone companies face. This is on the basis that the participants in their marketplace should already have the necessary commercial trading licenses onshore.

On the other hand, for pharmacies or beauty stores that intend to sell their products online through their websites, it is necessary to have a presence onshore.

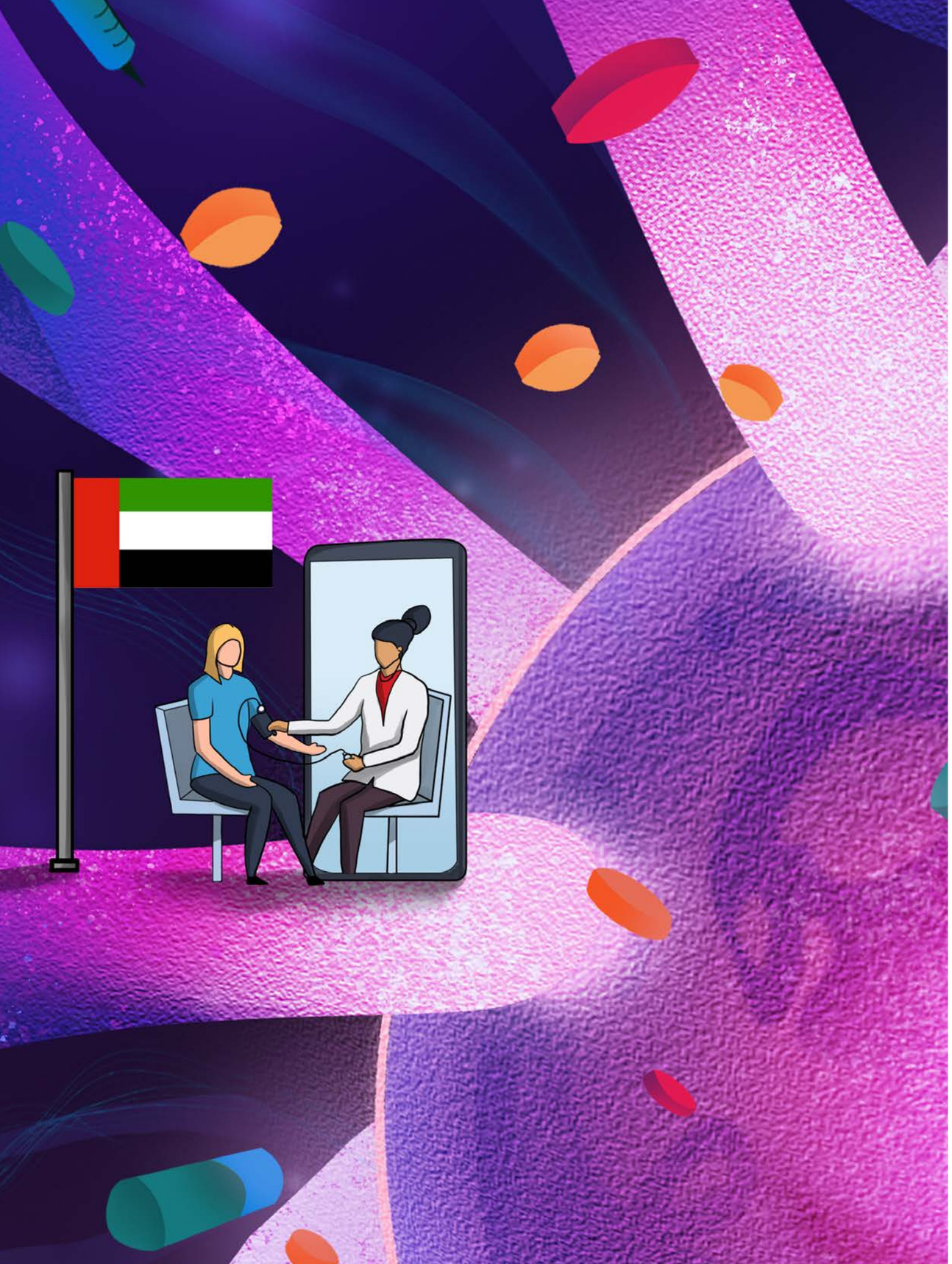
For an onshore presence, foreign investors must partner with a UAE national (either an individual or a company wholly owned by UAE nationals). The UAE partner must hold at least 51 per cent of the shares in the onshore company.

By contrast, setting up in a free zone offers 100 per cent ownership to foreign investors, which provides for a more attractive environment for many businesses.

To conclude, the nature of licenses/approvals that need to be obtained and the jurisdiction in which the corporate entity needs to be set up will depend on whether the online sale is being contemplated by an already registered pharmacy or beauty store in the UAE or through third-party e-commerce aggregators.

For further information, please contact healthcare@tamimi.com.

[2] *An onshore (or 'mainland') presence is one that is outside of a free zone.*



The regulation of telehealth in the UAE during COVID-19

Christina Sochacki
Senior Associate
Corporate Commercial
c.sochacki@tamimi.com

COVID-19 has spurred many changes this year; there does not seem to be any industry that has not been impacted. Within healthcare, one almost universal change, and I would argue extremely positive change, has been the lightning speed with which telehealth has been propelled forward. Telehealth has been a topic for decades but the adoption of telehealth regulations and insurance reimbursement for it have been slow, at best. Now, it is one of the greatest solutions to access to care issues during this global pandemic, and reducing the spread of the virus through decreased person to person interactions.

While the Emirates of Abu Dhabi and Dubai have in recent years implemented telehealth policies, COVID-19 really pushed the needle forward. Below we highlight the development in regard to telehealth in Dubai and Abu Dhabi.

As a brief background, the regulation of telemedicine is fragmented across the emirates, with responsible authorities including the UAE Ministry of Health and Prevention ('MOHAP') in the Northern Emirates, the Department of Health Abu Dhabi ('DOH') in the Emirate of Abu Dhabi, the Dubai Health Authority ('DHA') in the Emirate of Dubai (excluding Dubai Healthcare City), and the Dubai Healthcare City Authority ('DHCA') in the Dubai Healthcare City.

Emirate of Abu Dhabi

New telehealth standard

The DOH issued its initial telemedicine regulatory framework in 2014; since then, the industry has awaited updates to the same and a more comprehensive acceptance of new telehealth providers in the emirate. In September 2020, the DOH issued an updated DOH Standard on Tele-Medicine ('DOH Telemedicine Standard'), bringing Abu Dhabi's telemedicine standards in line with recent federal legislation, and current care delivery models. The standard sets out the minimum requirements for the provision of telemedicine services by DOH licensed providers, covering:

- telediagnosis;
- telecounselling;
- telemedical interventions;
- teleconsultation;
- teleprescription; and
- telemonitoring.

It remains that a DOH licence is required by the healthcare facility for the provision of telemedicine services, either to provide telemedicine services as a supplemental service or as the primary service. Stand-alone telemedicine providers however, are not permitted to engage in telemedicine interventions and telediagnostic services.

The individual healthcare professional is not required to obtain a specific telemedicine licence; merely, the provider must be credentialed/privileged by a healthcare facility with a telemedicine licence in order to provide telemedicine services. This leaves the onus on the healthcare facility to ensure that its healthcare professionals engaging in telemedicine services have the appropriate skills, training, knowledge, and technological infrastructure to deliver the services.

1. Telediagnosis

Telediagnosis is further limited to being provided between a UAE licensed healthcare facility and the DOH licensed facility, through a formal contractual arrangement. The primary responsibility for the clinical and medical healthcare decisions in relation to the patient continues to reside with the originating facility that is seeking the telediagnostic service.

2. Telecounselling

The DOH Telemedicine Standard does open the door for certain telemedicine services to be provided across borders, with providers outside of the UAE, such as telecounselling. Although, and this is a big caveat, the sharing of healthcare data outside of the UAE requires authorisation from the DOH, as per the UAE Federal Law No. 2 of 2019 (see our November 2019 article entitled The Federal Law regulating the Use of Information and Communication Technology in the UAE Healthcare Sector, available at https://www.tamimi.com/law-update-articles/the-federal-law-regulating-the-use-of-information-and-communication-technology-in-the-uae-healthcare-sector/; see also our November 2020 article entitled You are in my system – The implementing regulations on Federal law regulating the use of ICT in the UAE healthcare sector, available at https://www.tamimi.com/law-update-articles/you-are-in-my-system-the-implementing-regulations-on-federal-law-regulating-the-use-of-ict-in-the-uae-healthcare-sector/. The primary responsibility for the clinical and medical healthcare decisions in relation to the patient continues to reside with the originating facility that is engaging in the telecounselling services. A written agreement (i.e. agreement, memoranda of understanding and/or contract) between the telecounselling services providers is expected. Such agreements and partnerships must be with healthcare entities demonstrating compliance with their country specific regulatory body, including having medical liability insurance. Further, and this may be a bit of a hindrance to some international providers providing their expertise to Abu Dhabi facilities, where a telecounselling partner is located outside of Abu Dhabi, the contractual relationship with that partner requires that partner to comply with the relevant country as well as Abu Dubai specific regulations. This could be interpreted to make the foreign partner and its providers liable to claims within Abu Dhabi, but we will keep an eye on this to see how it pans-out in practice.

3. Telemedical interventions

In relation to telemedical interventions, the primary responsibility towards the patient resides with the healthcare professional and facility where the medical intervention is taking place. It is unclear whether this means the place at which the physician is manipulating the robot or where the patient is located. Another section of the standard indicates that the primary responsibility for clinical and medical healthcare decisions resides with the facility where the patient is located. Clarity is required in this regard, where the distant facility's responsibility begins and ends and where the local facility sits, as this will certainly impact the agreements in place between the facilities, as well as providers' willingness to engage in telemedical interventions.

The physician performing the telemedical intervention should be licensed by the DOH, if located in Abu Dhabi, or by the respective regulatory authority in the UAE or country specific regulator, if located outside of the UAE. Further, it is required that a licensed healthcare professional is with the patient at all times, ready to intervene in the event of failure in the tele-robotic system, including handling the robot at the intervention site.

Only assistive technology, not autonomous technology replacing the healthcare professional, is permitted. The tele-robotic system must be operated and controlled by the healthcare professional. Further, the telemedicine intervention system must be a clinically approved system with international certification and/or approval agencies recognised by MOHAP.

4. Teleconsultation

In accordance with 2019 federal law updates (see our section below), teleprescription is now permitted. Further, it is permitted to issue one day of sick leave by teleconsultation, given that it is not an extension of an existing sick leave and is not issued retroactively. This will greatly cut down on the burden of sick individuals needing to leave their home, interact with others, and/or visit a doctor in person for short illnesses (such as influenza or gastroenterological infections). Further, providers may apply to the DOH for approval of teleconsultation medical services that are not currently listed in the standard, such as structured patient education, disease management counselling and services, rehabilitation, speech, and physical therapy.

5. Teleprescribing

Teleprescribing for non-urgent and non-emergency medical conditions is now permitted by healthcare facilities that have been licensed by DOH to provide teleconsultation services. Systems must be in place to allow prescribers to add electronic signatures on the prescription. Further, the prescription should be issued through the HIS system of the facility, and submitted electronically to the associated pharmacy with access to the HIS system. In the absence of an associated pharmacy with access to the HIS system of the facility, then an original prescription must be issued and collected from the facility. Prescription of controlled, semi-controlled, and narcotic medications will continue to have the limitations put in place by federal laws and DOH regulations.

6. Telemonitoring

Telemonitoring involves the use of 'devices and supporting systems used to automatically transmit signals from patients to a central station where abnormalities will trigger a response by healthcare professionals or those that support the monitoring data quality, utilisation management review, and risk management'. In addition to the general duties of telemedicine providers, providers of telemonitoring services must: 1) ensure that telemonitoring services are offered in at least Arabic and/or English languages; 2) uphold the principles of consent to also include consent for: a) monitoring and sharing of data; and b) surgical insertion of monitoring devices; and 3) incorporate clinically relevant telemonitoring data forms into the EMR. There are also additional technical, technology and equipment, and data related, as well as clinical and quality governance, requirements.

COVID-19 related changes

The DOH Telemedicine Standard is in addition to and supplements the circulars issued over the past few months in relation to DOH's COVID-19 response. One such development was the mandate that telemedicine is required to be a benefit in all insurance products, until further notice.

Telehealth has been a topic for decades but the adoption of telehealth regulations and insurance reimbursement for it have been slow . . . COVID-19 really pushed the needle forward.

Another such development was the launch of the DOH Remote Care Platform for virtual care visits for certain approved specialisations (which includes psychotherapy services). It aims to provide safe, convenient, and equitable access to healthcare. This was instituted as a temporary measure to allow those providers that have enrolled in the DOH Remote Care Platform to provide telehealth services, particularly to Thiqa and Basic healthcare plan patients, without the need to undergo the usual DOH telehealth licensing process. The registration process provides for automatic approval, with the caveat that controlled medications require special approvals by DOH before they may be delivered to the patient's home. Beside the special requirements for controlled medicines, teleprescription and delivering of medications is permitted (and encouraged) through the platform. DOH's intention is that this is a temporary measure, following which formal licensing will be required once the pandemic is deemed to be over.

Of note is that the DOH has waived the requirement for (a) and (b) Basic insurance package patients to first seek care from a general practitioner prior to being referred to a specialist. On the DOH Remote Care Platform, Basic members may seek treatment directly from specialists on the platform.

The DOH has confirmed that verbal consent to the telehealth consultation is sufficient, as long as it is documented by the provider in the patient's medical record, as per the DOH Telemedicine Standard. Utilisation restrictions are in place however, in accordance with the DOH Claims & Adjudication Rules.

For outpatient pharmacies seeking to provide home delivery of medications, an automatic three month temporary approval will be granted by the DOH upon application, following which an application for permanent licensing must be obtained. At all times, such pharmacies are required to comply with the DOH Standard on Delivery of Pharmacy Medications. All home deliveries are to be based on a prescription and are without utilisation limitations. There is to be no co-payment or co-insurance collected from members of any health insurance scheme in Abu Dhabi for telemedicine or telepharmacy services.

Historically, the DOH issued a telemedicine licence to the Abu Dhabi Telemedicine Centre as a "pilot", but generally did not issue further stand-alone telehealth centre licenses. Thus, while the regulatory framework required that a healthcare facility seeking to provide telehealth services in Abu Dhabi obtain a DOH telehealth licence (either as part of an existing healthcare facility or as a stand-alone telehealth centre) to do so, in practice, such licenses were not readily granted. Thus, the DOH Telemedicine Standard is a highly welcomed development.

Emirate of Dubai

The DHA issued its first telehealth regulation in 2017 and revamped the same in 2019. Our November 2019 article (see DHA Issues New Standard for Telehealth Services, available at https://www.tamimi.com/law-update-articles/dha-issues-new-standard-for-telehealth-services/) highlights the key elements of the 2019 DHA Telehealth Standard. Since then, the DHA has issued a slew of circulars addressing exemptions and insurance coverage afforded during these current times.

For example, DHA General Circular No.9 of 2020, on teleconsultation DSL Codes established five new Dubai Service List ('DSL') codes for billing purposes to cater to teleconsultation services, with effect from 5 April 2020. The codes included those for teleconsultation with a general practitioner, specialist, consultant, allied health provider, and psychotherapy (psychologist) however, it does not include nursing consultations.

All categories of general practitioners, specialists, and consultants conducting teleconsultations will be covered in the respective codes. All service providers, insurers, and third party administrators are encouraged to begin discussions on pricing immediately. As per Policy Directive No. 2 of 2020, all payers must encourage and accept any claims, regardless of whether they had previously not agreed to telehealth services from the same network providers. To clarify, the directive does not mandate the default inclusion of any telehealth providers licensed by DHA who is not part of a payers' network; rather, the directive applies to those network providers with whom the payer has not extended telehealth services previously, which should now be included. The objective is to reduce unnecessary patient visits to medical facilities, where possible, during the COVID-19 pandemic.

Federal Medical Liability Law

An annex to the 2019 Federal Medical Liability and Practice of Human Medicine Resolution set out the Federal rules for governing telehealth services, the first piece of federal legislation to support the initiatives, implemented years prior thereto, by the DHA, DOH, and DHCA. The resolution provides necessary additional details to implement the provisions of the Medical Liability Law (Federal Law Decree No. 4 of 2016 concerning medical liability). The Resolution also sets out the terms and conditions for the provision of remote health services, solidifying, at the federal level, the permissibility and parameters for providing telehealth services in the UAE.

We further discuss this resolution in our November 2019 Law Update article entitled Significant Developments: UAE Medical Liability Law, available at https://www.tamimi.com/law-update-articles/significant-developments-uae-medical-liability-law/.

Conclusion

Whether the quick and widespread adoption of telehealth and associated regulations is here to stay or will be scaled back post-pandemic is yet to be seen. As the current environment has pushed both regulators, and patients alike, to become more comfortable with remote care delivery models, we expect it to become a standard offering. We also expect to see further regulatory developments in the way of: data localisation laws and providing for necessary exemptions; more robust data privacy regulations; and further guidance on the use of artificial intelligence and cloud storage in the healthcare industry.

For further information, please contact healthcare@tamimi.com.

UAE counterfeit medical products: tightened measures to address an ever increasing problem

Rasha Al Ardah
Senior Associate
Intellectual Property
r.alardah@tamimi.com

As the pandemic hit the world eariler this year, counterfeiters immediately took advantage of the situation, and markets in different parts of the world were full of counterfeit facemasks, hand sanitisers and unauthorised antiviral medication, in addition to many other products. In a worldwide operation for Interpol (Operation Pangea XIII) in March this year, US$14 Million worth of pharmaceuticals were seized. The seized products included 4.4 million units of illicit pharmaceuticals worldwide and more than 37,000 unauthorised and counterfeit medical devices, such as surgical masks and self-testing kits (HIV and glucose). Of course the online market made it easy to distribute such products on a wider scale.

Counterfeit medical products is not a new problem. According to World Health Organization statistics, an estimated 1 in 10 medical products in low - and middle-income countries is falsified. Counterfeit medicine is defined by the World Health Organization as "a medicine, which is deliberately and fraudulently mislabelled with respect to identity and/or source". Counterfeiting can apply to both branded and generic products and counterfeit products may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient ingredients or with fake packaging.

Effect of counterfeit medical products

Counterfeit or falsified medical products appear very similar to the original but the effectiveness and/or treatment failure thereof may trigger suspicion. Due to the ineffectiveness of counterfeit medications, a patient may not see any improvement and his or her condition may even deteriorate. In addition, such counterfeit medication may cause drug resistance and possibly even death. A counterfeit medical device may well have disastrous results; for example, a counterfeit glaucous testing strip may give a wrong reading to a diabetic patient, causing the patient to take the wrong level of insulin, which may possibly cause death.

On the other hand, a patient's inability to receive the proper treatment may increase negative analytical feedback because they were not cured or healed and that, on its own, could potentially affect the original pharmaceutical business that will likely receive negative reviews thus causing harm to the business.

The number of counterfeit medical and pharmaceutical products allegedly results in loss of revenue worth billions of dollars to pharmaceutical companies, and in ill health and sometimes death of patients. It is estimated that more than 700,000 deaths per year worldwide occur due to fake anti-malarial and anti-tuberculosis drugs.

According to the World Health Organization statistics, an estimated 1 in 10 medical products in low- and middle-income countries is falsified

The situation in the UAE

Like any other country in the world, the UAE is not immune from such activities. Currently, the most common types of counterfeit medicines entering the market include lifestyle drugs, such as those addressing erectile dysfunction or weight loss. Since the pandemic started this year, enforcement authorities in the UAE have focused on all medical supplies. In a joint operation by the Dubai Police and the Dubai Department of Economic Development in April 2020, more than two million medical masks of unknown origin, tens of thousands of fake labels, packages, and covers for several brands, and thousands of thermometers were seized.

The UAE has increased its efforts to eliminate fake medicines and medical products from reaching consumers. Some of the initiatives made by the DOH include the use of a device that detects counterfeit medicines in about seven seconds. Earlier this year, the Department of Health announced that a new app that detects counterfeit medical products on sale in the UAE will be launched. The Dubai Health Authority, in its turn, announced the launch of a pharmaceutical track and trace system to closely monitor medicines manufactured in the UAE and elsewhere along the supply chain to in order to eliminate fake drugs.

Legislative perspective

In this section, we have addressed the key applicable laws.

Trademark Law

Intellectual property laws in the UAE have addressed counterfeit medical products. The Federal Trademarks Law No. 37 of 1992 and its amendments ('Trademarks Law') penalise anyone who deals with counterfeit products. Article 37 of the Trademarks Law provides for a penalty of imprisonment and a fine not less than AED 5,000 (approximately US$1,400), or either of these two penalties for:

"(1) Any person counterfeiting a duly registered trade mark or imitating it in such a way as to mislead the public in respect of goods and services distinguished by the original mark or the mark resembling it, as well as any person knowingly makes fraudulent use of a counterfeit or imitated trade mark;

(2) Any person who in bad faith uses a registered trademark belonging to another person on his products or uses such mark wrongfully;

(3) Any person who knowingly sells or offers for sale or distributes or possesses for the purpose of sale products bearing a trade mark which is counterfeit, imitated, or wrongfully affixed as well as any person who knowingly provides or offers services under a trade mark which is counterfeit, or imitated, or wrongfully used. "

Based on the Trademarks Law, enforcement authorities including Customs, Department of Economic Development, Ministry of Health and Prevention, and Police, have been conducting raids, seizing counterfeit medical products, and destroying the same.

The UAE has increased efforts to eliminate fake medicines and medical products from reaching consumers.

Pharmacy Law

In December 2019, Federal Law No. 8 of 2019 on Medical Products, Pharmacy Profession and Pharmaceutical Establishments was issued. It replaced Law No. 4 of 1983 on the Pharmacy Professional and Pharmaceutical Establishments and Law No. 20 of 1995 on the Drugs and Products.

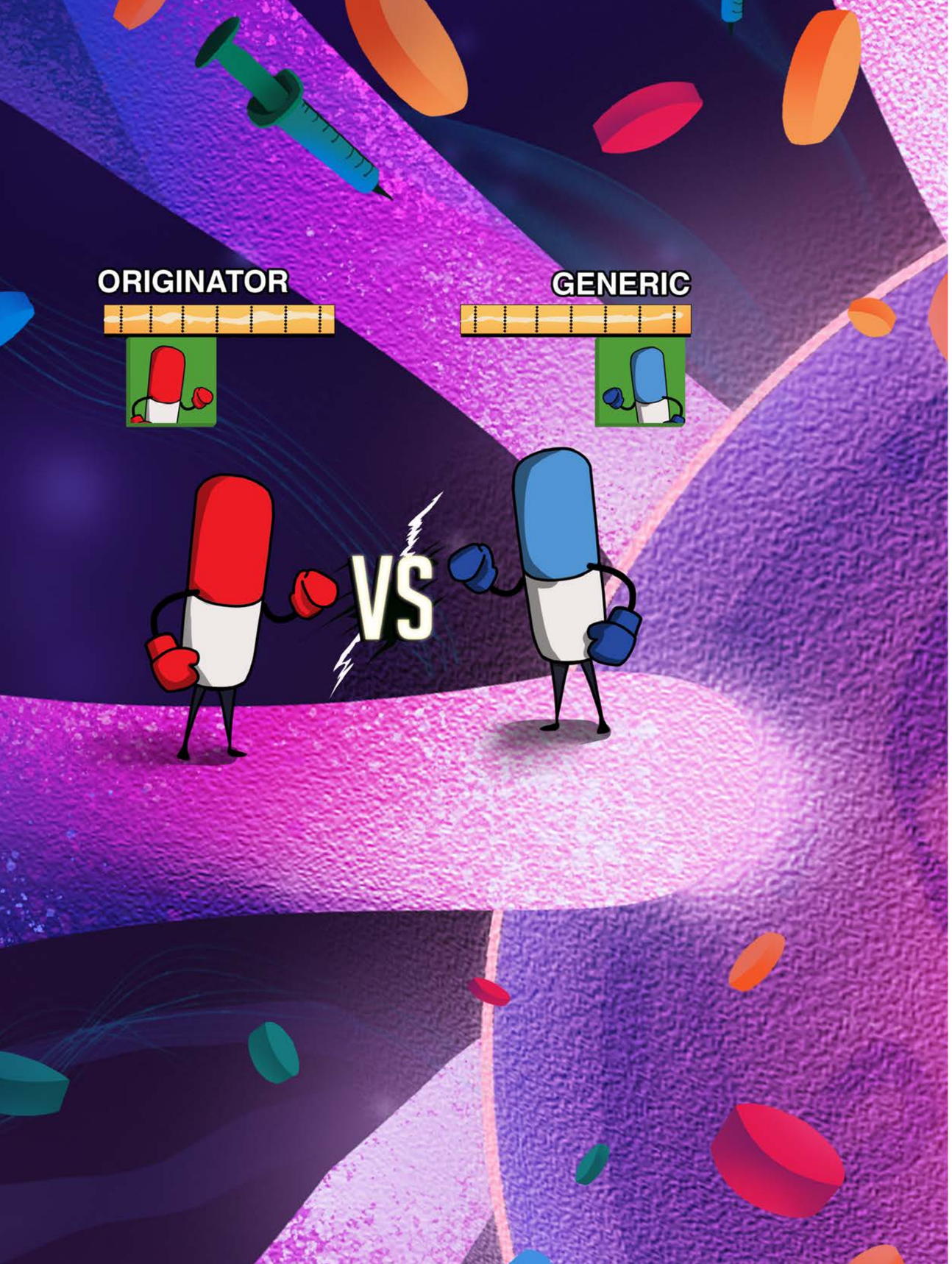
Pursuant to this law a 'Counterfeit Product' is defined as: "A product that is deliberately and fraudulently produced with intent of deception and fraud, including:

1. providing its cover, packing, identification label, or patient information leaflet with false or incorrect information in regards to its identity or origin and in a means not identical to the reality;
2. counterfeiting another drug using the same technical design, cover colours, packaging, and identification label of the original product;
3. addition or removal of an active or non-active ingredient(s) of the drug's formulation prescribed on its cover, packaging, identification label, or patient information leaflet without the permission of the competent department; and
4. change the volume or quantity of its active or non-active ingredient(s) without the permission of the competent department.

The law has provided for increased penalties for dealing with counterfeit medical products. Pursuant to Article 110, a penalty of imprisonment and/or a fine of at least AED 200,000 (approximately US$5,500)) to at most AED 1,000,000 (approximately US$272,000)), would be imposed for whoever falsifies or imitates a medication, raw materials, chemicals, health foods or therapeutic cosmetics, or knowingly sells to third parties or illicitly imports or smuggles the same into the country. More severe penalties may be imposed, including the closure of the business for a period of three months or full closure with licence suspension, and the confiscation of all violating products.

The UAE has taken serious measures and steps in its fight against counterfeit medical products by, for example, introducing the latest technologies to prevent counterfeit products from entering the country and reaching customers as well as levying hefty penalties for dealing with counterfeit medical products, all of which aim to eliminate counterfeit medical products in the market.

For further information, please contact healthcare@tamimi.com.



Protecting medicinal and pharmaceutical products in the GCC: Originators Vs. Generics

Ahmad Saleh
Partner, Head of Patents & Designs
(R&D and Innovations)
ah.saleh@tamimi.com

UmmeSalamah Tyebjee
Patent Analyst
Intellectual Property
u.tyebjee@tamimi.com

The drug patent system in the GCC region is fairly robust and provides an expedient way for pharmaceutical entities to secure patent rights in the various GCC countries, thereby preventing generic companies from entering the pharmaceutical markets.

Pharmaceutical products are particularly protected through the protection of novel chemical compounds, medical substances, pharmaceutical compositions, active agents, and other medical substances as well as through the protection of new and innovative processes used for obtaining such medicinal products. Pharmaceutical products can also be protected by any new crystalline forms (polymorphs) of the active ingredient having desirable physical properties, such as improved stability, increased bioavailability, and/or enhanced therapeutic efficacy. In most GCC countries (except Oman), methods of surgical or diagnostic, or therapeutic treatment on humans or animals are yet not considered patentable subject matter and cannot be pursued for patent protection.

Over the past few years, the GCC countries have updated and amended their patent laws, particularly aligning them with internationally recognised practices. Second medical use inventions and Swiss type claims, which were previously considered to not be patentable, are now allowed and accepted in most GCC countries. The patent laws of Oman and Bahrain specifically provide for the patentability of the second medical use of a known drug (compound or composition). Although not provided by law, the GCC Patent Office, along with the Saudi Arabia and the UAE patent offices, have recently started accepting patent applications with second medical uses, provided the pharmaceutical compound for which the second medical use is claimed to be novel.

Regulatory exclusivity - recognising patents of origin

Regulatory exclusivity is not recognised by the GCC countries. GCC countries require a pharmaceutical entity to have local patent protection for their drugs in order to prevent a generic from entering the pharmaceutical market and seeking a marketing authorisation from the relevant Ministry of Health. This means that even though a pharmaceutical entity has a valid patent in any other part of the world, they cannot claim the equivalent protection based on that patent (patent of origin) in the GCC countries.

In the past, the UAE did recognise patents of origin and allowed a pharmaceutical entity to claim equivalent patent protection to block the approval of a generic company attempting to

seek marketing approval for the introduction of a generic competing drug in the UAE market (as per the Ministerial Decree 404 of 2000 ('Decree 404').

However, certain changes and uncertainties have arisen around the application of Decree 404 over the last couple of years; a new decree was issued on 21 September 2020 by the UAE Ministry of Health & Prevention ('MOHAP') under the name of Ministerial Decree 321 of 2020 ('Decree 321'). According to Decree 321, patents of origin are indirectly rejected as a means of protecting registered drugs inside the UAE with the exception of products registered or which have obtained marketing approval from MOHAP before the date of publication of the Decree 321 in the UAE Official Gazette, which is expected to occur during October 2020. Decree 404 will however, continue to apply to drugs registered or approved before the publication date of the new Decree 321.

The Saudi Food and Drug Authority ('SFDA') published a consultation report in September 2020 for receiving recommendations and comments on certain procedures related to the protection and registration of pharmaceutical products. It is still to be seen how the new regulation will address patents of origin in KSA however, our expectation is that patent linkage will be rather limited to local patent protections valid inside KSA, either through a KSA patent or a GCC patent.

Hence, in order to prohibit generics from entering the market, it is highly recommended that the product or drug be protected by way of registering its patent at the respective patent offices.

Data exclusivity

Patents and data exclusivity work in a correlative fashion but are distinctly different vehicles of protection from one another. Patents are granted by the patent office (of the country where the patent application is being filed) anywhere along the development timeline of a drug and may comprise a wide range of claims. Data exclusivity protects data submitted by the originator company in support of their innovator drug, which cannot be used by a generic company for seeking approval of an equivalent generic drug during the data exclusivity protection period. This can run concurrently with a patent or not. Data exclusivity is a statutory provision and is granted to a pharmaceutical entity for a new drug application when the statutory requirements are met. Data exclusivity provisions ensure a balance between novel drug innovation and generic drug competition.

Regulatory approval for pharmaceutical products requires pharmaceutical entities to furnish data about the efficacy and safety of their product to the respective regulatory authorities. Any pharmaceutical entity applying for such approval for the first time needs to provide detailed, substantial information in addition to the clinical test data pertaining to the product for which such an approval is sought.

Usually, generic companies that subsequently wish to seek approval for marketing a generic drug (same as that of the originator) rely on information filed by the originator pharmaceutical company that made the first application. In order to be able to benefit from the data provided by the originator in their regulatory filings for a particular medicinal product, a generic company must show that their product has the same qualitative and quantitative composition as that of the originator product and that the generic drug is the originator drug's bioequivalent.

By providing data exclusivity, an originator company enjoys a particular stipulated period during which their pre-clinical and clinical trials data provided to the regulatory authorities for seeking an approval is kept confidential and is not to be referenced in the regulatory filings of another company (typically a generic company) for the same drug substance.

Some of the GCC member states also provide for provisions of data exclusivity in their laws. Amongst the various GCC countries, the United Arab Emirates, Saudi Arabia, Oman, and Bahrain provide for such data exclusivity provisions in their laws. Generic companies, prior to applying for marketing approvals from the relevant ministry of health, must ensure that there is no valid patent protection in that country for that particular drug.

The recognition of data exclusivity by some of the leading GCC countries, in addition to the robust patent laws, has led to a tremendous increase in the number of pharmaceutical patents being filed in the region. Each GCC country has its own regime with respect to the protection of clinical data submitted by originators, and patent linkage.

Pharmaceutical registration and marketing approvals

In the GCC countries, importation and distribution of pharmaceutical products, be they originator drug or generic, is subject to the supervision and approval by the relevant governmental entity in each country, namely the relevant ministry of health, food and drug administration or authority, or other authority depending on the country. The GCC does not have a centralised governmental body regulating the importation and distribution of pharmaceutical products inside the region, and therefore marketing approval must be sought separately for each one of the GCC countries according to applicable national laws and regulations. In general, and subject to limited exceptions, no pharmaceutical product, whether an originator or a generic product, can be marketed, distributed, sold, offered for sale, and/or imported without seeking prior approval for the same from the relevant authorities, and registration of a pharmaceutical drug with the relevant ministry of health is generally mandatory, irrespective of whether such a drug is protected by a patent. We believe that GCC countries will be taking increasing measures for balance patent protection and generic entry through the introduction and regulation of patent linkage processes and systems.

Prior to seeking or applying for such marketing approvals, generic companies must ensure that there is no valid patent covering the drug product for which they are seeking marketing approval.

Pharmaceutical patent enforcement

Pharmaceutical patent enforcement in the GCC is governed through local federal courts and by the patent laws of the respective GCC countries where the infringement activity is taking place. There are no unified courts relating to GCC patent matters. The authorities of each GCC member state must examine all disputes relating to infringement or imminent infringement of pharmaceutical patents and such disputes must be settled in accordance with the provisions of the local patent laws and regulations governing national patents (if any). During patent enforcement and litigation, it must be noted that courts of the various GCC countries may take into consideration decisions from foreign courts or international bodies specifically for cases relating to technical subject matter. However, the local courts are not bound by these decisions.

Enforcement of patents in the region, as is the case in all emerging and developing countries, requires a steep learning curve and is often met with certain challenges, some of which are the country's limited expertise in dealing with patent cases, lack of precedents, lengthy proceedings, absence of awards for indirect damages, high costs of translations, and other legal formalities.

In the past several years, the GCC countries have come a long way in enforcing their patent laws and making sure that the patent rights of owners are protected in the market. But what remains to be done is to develop specialised courts with a specific focus on patent litigation and infringement matters. Although, at present, the overall regional experience with infringement and litigation regarding patent applications is small, the same is expected to rise in the near future, considering that the authorities of these countries are actively working towards the development of specialised courts, legal advisors, and judges to handle and preside over patent litigation matters.

Conclusion

The goal of the patent laws and data exclusivity provisions in the GCC region is to mainly allow the originators to recoup their heavy R&D investment and prevent the generics from entering the pharmaceutical market and consequently drive down the market prices during the lifetime of their patents. Through patenting or data exclusivity, the originator or pharmaceutical companies today have the option of safely and securely penetrating the rapidly growing pharmaceutical market of the GCC region. The new Decree 321 and the consultancy document issued by the SFDA in September 2020 are aligned to set a fair balance between a strong IP regime protecting the interests of innovators and originators and a generic pharma market with an enhanced regulated and transparent marketing penetration process and rules.

As matters currently stand, we encourage pharmaceutical originators to file patent applications covering their drug products or composition's inventions as the chances of securing patent protection for these are fairly good, in addition to excluding the generic companies from marketing and distributing the drug in the market. More applications will also increase awareness around the importance of such inventions for originator companies and will help in weighing the balance in favour of further protection for such inventions during any future reviews of the law by the competent legal authorities.

For further information, please contact healthcare@tamimi.com.

The new UAE Resolution concerning the Supreme Committee of Medical Liability

Ahmed Allouz
Partner, Head of Litigation – Dubai
a.allouz@tamimi.com

Amro Hassan
Associate
Litigation
a.hassan@tamimi.com

Introduction and background

The UAE Council of Ministers issued a new resolution concerning the Supreme Committee of Medical Liability (the 'Supreme Committee') (Resolution No. 14 of 2020) (the 'New Resolution'). This resolution supplements the new Medical Liability Law (Federal Decree-Law No. 4 of 2016) with the role of considering grievances regarding reports of the Medical Liability Committee(s) set forth in Article 18 of the new Medical Liability Law. (See our article for further background on the new Medical Liability Law, The New UAE Medical Liability Law: An Analysis at https://www.tamimi.com/law-update-articles/the-new-uae-medical-liability-law-an-analysis/.)

By way of background, a supreme committee of medical liability was previously formed under the ministerial resolutions that were issued based on the former Medical Liability Law (Federal Law No. 10 of 2008). That committee was formed to provide its technical opinion in medical malpractice cases upon the request of the Public Prosecution, the UAE courts, or the health authorities. Healthcare professionals and patients previously also had the right to request the court or the Public Prosecution to refer medical malpractice cases to it prior to the formation of the supreme committee or a specialised medical committee to be formed by one of the relevant health authorities.

However, the new Medical Liability Law (Federal Decree-Law No. 4 of 2016) has introduced a new medical liability committee (the 'Medical Liability Committee') to review and opine on medical malpractice cases before they are decided by the judicial authorities, and the Supreme Committee whose role is primarily to review grievances filed by both patients and healthcare professionals against the reports of the Medical Liability Committee.

The new Medical Liability Law provides that the supreme committee referred to in the former Medical Liability Law shall continue to settle the files referred there to up until the date of formation the Medical Liability Committee. The formation of the Medical Liability Committee occurred after the issuance of the Executive Regulations of the current Medical Liability Law (Council

of Ministers' Resolution No. 40 of 2019) in July 2019. (See our article on the Executive Regulation, Provisions of the new resolution regarding medical liability in the UAE at https://www.tamimi.com/news/provisions-of-the-new-resolution-regarding-medical-liability-in-the-uae/.) Following this, the New Resolution was issued in March 2020 establishing the Supreme Committee to consider grievances against reports of the Medical Liability Committee(s) set forth in Article 18 of the new Medical Liability Law. We will outline some of the key provisions of this 12-article resolution in the next paragraphs below.

Formation of the Supreme Committee

The New Resolution provides in its second Article 2 that the Supreme Committee shall be formed by medical consultants from specialist areas to be identified by a resolution of the Minister of Health and Prevention. The same Article states that the Minister shall also nominate the Supreme Committee's members, chairman, and vice-chairman by way of a resolution.

Grievance consideration procedures

Following the filing of the grievance, the relevant health authority will refer the grievance to the Supreme Committee. Pursuant to Article 3 of the New Resolution, the Supreme Committee shall, after examining the grievance, draw up a reasoned report expressing its opinion on the grievance, which shall include the following:

1. the standard on which the alleged medical error committed is deemed to be based and considered a gross medical malpractice;
2. indicating elements available in the file confirming the occurrence of a gross medical malpractice; and
3. indicating the type of damage and malpractice.

Article 3(3) of the New Resolution provides that the Supreme Committee may uphold the report of the alleged medical liability and may also reject, adjust, or cancel the grievance. The said Article also provides that the Supreme Committee's report shall be final and unchallengeable by any means before any authority.

Supreme Committee's rapporteur and secretaries

Article 5 states that the Supreme Committee's office shall be in the Ministry of Health and Prevention. It also allows the Minister to issue a resolution appointing employees to assume the functions of the Committee's rapporteur and secretaries under the supervision of its chairman.

The functions of the Supreme Committee's rapporteur include, among other things, receiving grievances referred by the relevant health authority to the Supreme Committee, inviting the members to attend meetings in co-ordination with the Supreme Committee's chairman or, in case of his absence, with the vice-chairman, collecting documents required by the Supreme Committee from relevant bodies, drawing up the minutes of meetings, and writing the Supreme Committee's report and sending it to the relevant health authority once signed by all the Supreme Committee's members.

Convening and voting quorum

According to Article 6 of the New Resolution, the Supreme Committee shall meet at the invitation of its chairman (or, in case of the absence of the chairman, at the request of its vice-chairman) to consider the grievances referred to it. Article 6 further deals with the required convening and voting quorum; it states that the Supreme Committee's meeting shall be valid only if attended by two-thirds of members, including the chairman or vice-chairman, that the Supreme Committee's report shall be issued by the majority of the members present and that, in the event of a deadlock, the meeting chairman shall provide the casting vote. However, in case of a gross malpractice, the report shall be approved by two-thirds of the members present.

Accordingly, the New Resolution was issued in March 2020 establishing the Supreme Committee to consider grievances regarding reports of the Medical Liability Committees set forth in Article 18 of the new Medical Liability Law.

Authorities of the Supreme Committee and time period for issuing the report

Article 7 of the New Resolution authorises the Supreme Committee to invite any person it deems necessary to discuss the grievance subject matter, review documents in the hands of the relevant bodies, form specialised sub-committees from among its members or from others to express the technical opinion on grievances presented to it.

The Supreme Committee is also allowed to seek the opinion of experts and consultants on grievances presented thereto, without having a counted vote.

Article 7 further directs the Supreme Committee to present its report to the relevant health authority within 30 days from the date on which the grievance was referred to it. However, the date may be extended to a further similar period or periods upon the approval of the relevant health authority at the Supreme Committee's request.

Members of the Supreme Committee: applicable law and oath requirements

According to Article 8, the rules applicable to experts before judicial authorities shall apply to the Supreme Committee's members, in so far as they do not contradict the provisions of the Medical Liability Law.

Article 8 also provides that each member of the Supreme Committee shall take the legal oath for one time before a federal department of appeal at which his/her place of residence is located before practising his/her work on the committee.

Conclusion

The formation of the Supreme Committee ensures that patients and healthcare professionals and facilities involved in medical malpractice actions will have a second chance to present their case and defend themselves, as applicable. This is expected to achieve a reasonable balance among injured patients, and medical professionals and facilities accused of medical malpractice, in that: (i) patients' claims will not be dismissed; and (ii) medical professionals and facilities will not be found guilty of medical malpractice until the Supreme Committee issues a final report in the grievances filed.

In addition, the New Resolution directs the Supreme Committee to clearly mention the basis on which it considered the medical error to be of a gross nature and the elements available in the file supporting the findings of a gross medical malpractice. This requirement ensures that gross medical malpractice, which may cause serious legal consequences, will not be attributed to healthcare professionals and facilities unless properly justified.

Finally, although the New Resolution provides that the Supreme Committee's report shall be final and unchallengeable by any means before any authority, we are yet to see how the courts will deal with challenges made by the parties against any deficiencies attributed to the Supreme Committee's reports.

For further information, please contact healthcare@tamimi.com.

In case you missed it: Key UAE healthcare laws and regulatory developments of 2020

James McMillan
Senior Associate
Corporate Commercial
j.mcmillan@tamimi.com

Clare Heaney
Associate
Corporate Commercial
c.heaney@tamimi.com

In 2020 the healthcare sector has been hit very hard by the arrival of the COVID-19 pandemic. The health regulators have issued numerous instructions to public and private sector operators on the handling of the situation. A number of these measures are discussed in this article, but this is not an exhaustive account of the collective effort to fight COVID-19. Further, we have highlighted a quick summary of the new laws and regulations which we have been monitoring. Many of these will require healthcare facilities to update their internal policies to reflect the provisions of the law or regulation.

COVID-19 related regulations and guidelines

The National Guidelines for Cinical Management and Treatment of COVID-19

These guidelines were issued by the UAE Ministry of Health and Prevention ('MOH') to provide a protocol on the practical steps to deal with COVID-19 cases as follows:

1. detail the measures necessary to protect hospital staff, patients, and visitors; and
2. outline the prognostic factors and markers for a severe COVID-19 disease, detailing the medications that may be prescribed and their possible side effects.

These guidelines are not intended to override the clinical decisions that will be made by clinicians providing individualised patient care.

DOH Circular No. 46 of 2020 on COVID-19 Research and Clinical Trials

This Circular was issued by the Department of Health Abu Dhabi ('DOH') for the sake of the safety of patients participating in medical research and clinical trials in general and, in particular, in research related to COVID-19 treatment. The DOH requires that all health facilities adhere to the following:

1. prevent overlaps of clinical trials to ensure patients' safety;
2. under no circumstance should patients enroll or participate in more than one clinical trial simultaneously,

unless there is a clear protocol for compassionate use outlined in the original clinical trial proposal;

3. all Principal Investigators ('PIs') and clinical trials' staff must strictly adhere to documentation of events on patients' files;
4. in order to enhance clinical trials monitoring at DOH level, all PIs must submit clinical outcomes (recovery, no change, death, and adverse events) during the course of approved clinical trials to DOH;
5. all clinical trials involving the use of immunomodulators and drug therapies must be carefully reviewed, monitored, and documented;
6. mortality and data review on an ongoing basis for all COVID-19 related deaths must be kept;
7. DOH will conduct further investigations and reviews to determine causality.

DOH Circular No.12 of 2020, Permitting Health Care Professional Rotation between AUH Facilities

To further help fight COVID-19, the DOH issued this Circular that allows all DOH licensed health professionals to work and move between DOH licensed health facilities as deemed necessary, regardless of the facility to which the professional is licensed. This is in line with a ministerial resolution issued to this effect and is valid until December 2020. A documented agreement between both healthcare providers is required, which must be non-profit and free of charge.

DOH Circular No.10 of 2020, on the Activation of Tele-medicine Services and Medicines Delivery to Homes in Abu Dhabi

This Circular was originally implemented in March 2020 and has been extended each month, with the latest circular extending it until 23 October 2020. It permits healthcare providers to temporarily provide tele-medicine services without a permanent telehealth licence from the DOH. Following the conclusion of the Circular's validity, a permanent licence will be required, as per the DOH Telemedicine Standard.

DOH Circular No. 106 of 2020, Extending Medical Home Visits for High Risk Patients

Where the original circular was issued in April 2020, this Circular provides for the extension, until the end of the year, of medical home visits for coronavirus high risk categories under all health insurance policies and schemes where telemedicine services cannot be provided. High risk categories include those over 60 years old and those with underlying medical conditions.

DHA Circular No 1176 of 2020, Permitting The Movement of Health Care Professionals Between Facilities In Dubai

Similar to the DOH Circular No.12 of 2020, the Dubai Health Authority ('DHA') issued this Circular to allow all DHA licensed health professionals to work and move between DHA licensed health facilities as deemed necessary, regardless of the facility with which the professional is licensed. In case of a medical complaint or malpractice, the medical liability lies between the professional and the facilities where the medical services have been offered. Moving between health facilities should be based on a written agreement between the relevant health facilities and professionals. This circular is in effect until cancelled by the DHA.

General

Further, to the above mentioned COVID-19 related regulations and guidelines, there have been interesting developments in other areas of healthcare as follows:

DOH Standard on Delivery of Medications

In February 2020, the DOH issued this Standard to outline the requirements that must be fulfilled when a DOH licensed outpatient pharmacy provides a delivery system for over the counter, pharmacy only, and prescription only medicines to their patients. It sets outs the obligations of the pharmacy in assuring the security and safety of delivery systems and ensures compliance with legal and regulatory requirements.

It lists the practical steps that must be performed by the representative of the pharmacy (delivery driver) to assure the security and safety of delivery systems. The Standard outlines that the delivery service may not include narcotics or controlled or semi-controlled drugs.

Federal Law No. 8 of 2019 on Medical Products, Pharmacy Profession, and Pharmaceutical Establishments; The Law was a significant development in the healthcare market in the UAE during January 2020.

Abu Dhabi Standard on Healthcare Data Privacy

The DOH issued a new policy on patient healthcare data privacy in September 2020 ('Data Privacy Standard'). The Data Privacy Standard addresses identifiable patient health information, also known as protected health information ('PHI'), setting the minimum data protection requirements including:

- circumstances in which PHI may be used or disclosed;
- secure and optimal use of PHI;
- operational policies, standards, and practices; and
- security and safety of PHI to maintain confidentiality, integrity, availability, and privacy.

The Standard applies to all categories of healthcare entities regulated by the DOH in the Emirate of Abu Dhabi, as well as healthcare professionals, insurance providers, service providers, vendors, brokers, and third-party administrators who have access to and are processing or storing PHI related to Abu Dhabi patients.

Entities are required to have a privacy policy and procedures in place that describe the way they collect, use, and disclose PHI, including guidelines on data collection, processing, security, localisation, and retention. Further, entities must communicate with relevant health authorities within 24 hours of initial knowledge of a data breach, and implement an incident response management plan and investigate the incident.

This standard comes in line with a number of regulatory developments in Abu Dhabi over the past couple of years in relation to technology and health information privacy and security. (See The Federal Law regulating the Use of Information and Communication Technology in the UAE Healthcare Sector at https://www.tamimi.com/law-update-articles/the-federal-law-regulating-the-use-of-information-and-communication-technology-in-the-uae-healthcare-sector/, The DoH Audit Program regarding Abu Dhabi Healthcare Information and Cyber Security Standards at https://www.tamimi.com/news/the-doh-audit-program-regarding-abu-dhabi-healthcare-information-and-cyber-security-standards/, A Healthy Start to AI Regulation at https://www.tamimi.com/law-update-articles/a-healthy-start-to-ai-regulation/, and Malaffi EMR Integration Required for All Abu Dhabi Healthcare Facilities https://www.tamimi.com/news/malaffi-emr-integration-required-for-all-abu-dhabi-healthcare-facilities/.)

Cabinet Resolution No. 29 of 2020 concerning Private Health Facilities

The Resolution issued on 15 April 2020 has been eagerly awaited as it provides the necessary detail to implement the provisions of Federal Law No. 4 of 2015 concerning Private Health Facilities (the 'Law').

The Law is applicable to all private health facilities in the UAE, including those operating in free zones.

The key provisions of the Law include:

1. the requirements for obtaining a licence for the operation or management of a private health facility in the UAE;
2. obligations in relation to insurance contracts, patient rights, qualifications, health and safety conditions, pricing, emergency plans, etc.; and

3. a framework for inspections, sanctions and penalties in case of non-compliance.

The issuance of the Resolution provides much needed clarity regarding the implementation of the Law. The Resolution helpfully clarifies the requirements for a licence to be issued and provides clarification regarding the management of the facility, depending on its classification (Article 9). Further, Article 7 of the Resolution sets out the necessary procedures and conditions in the event of a death of a private health facility owner. If the owner or a partner of the private health facility passes away, the ownership of or the stake in the same shall devolve upon the legal heirs within six months from the date of passing, based on a written application to be submitted by the heirs or their legal representative to the competent health authority.

Cabinet Resolution No 6. of 2020 concerning Cord Blood and Stem cells

The Resolution includes the rules and standards to be applied during the granting, collection, testing, processing, preservation, storage, distribution, import, export, and implementation of procedures related to cord blood and stem cells, and other nuclei cells derived from blood-forming cells, such as the bone marrow, peripheral blood, and cord blood.

This Resolution applies to all government and private health facilities at the country level that perform any of the activities covered by the scope of application and are responsible for any of these activities. These facilities are called, within the scope of application of this Resolution, 'Cord Blood and Stem Cells Storage Centres'. Cord Blood Storage Centres may be affiliated with a health facility or be an independent health facility specialising only in this area.

The Resolution provides that all facilities engaged in activities related to the use of primary human cells and stem cells must obtain a licence from the health authority within their jurisdiction (such as the DOH, DHA, Ministry of Health & Prevention, or the Dubai Healthcare City).

The licensed applicant must provide a bank guarantee of AED 10 million (approximately US$2.7 million), and in the event of a violation committed by the licensed facility, an amount commensurate with the nature of the violation committed shall be deducted from the guarantee, provided that the amount deducted due to the violation is returned to the bank guarantee balance by the licensed facility within two months from the date of the deduction.

Federal Law No. 8 of 2019 on Medical Products, Pharmacy Profession, and Pharmaceutical Establishments

The Law was a significant development in the healthcare market in the UAE during January 2020. This Law replaces Law No. 4 of 1983 on the Pharmacy Professional and Pharmaceutical Establishments and Law No. 20 of 1995 on the Drugs and Products. The Law seeks to establish a modern legal framework under which medical and health focused consumer goods are placed into the UAE marketplace.

Under the Law, a number of new requirements are set out in respect of licensing, pricing, post market surveillance, safety, clinical trials, and product registrations. One of the key takeaways is that a marketing authorisation holder must appoint one pharmaceutical establishment as an importer. However, it is noteworthy that the marketing authorisation holder is now able to appoint more than one distributor of the products in the UAE. Historically, import and distribution were carried out in the UAE by one registered agent or distributor.

Marketing authorisation and marketing authorisation holder are clearly defined terms under the Law. The marketing authorisation holder must be registered with the MOH and must adhere to the specific compliance obligations under Articles 3 to 12 of the Law. This includes designating a medical warehouse to import and distribute its products, and agreeing on a strict protocol with the MOH in relation to monitoring the products being sold in the UAE and reporting any incidents or side effects of usage. Medical product establishments in the UAE must be owned by a UAE National in accordance with Article 85 of the Law. The marketing authorisation holder must appoint one or more qualified persons residing in the UAE. The qualified persons must have medical or pharmaceutical qualifications and be licensed in the UAE. They will be jointly liable with the marketing authorisation holder in respect of compliance with the law. This is a shift in direction from the appointed local agent to direct accountability for pharmaceutical companies.

The MOH shall set up a supreme committee for clinical study ethics, which shall be responsible for medical ethics policies nationally. It is noteworthy that the Law has discarded the concept of a scientific office, which existed under the old law. The qualified persons appointed by the marketing authorisation holder is now responsible for providing scientific and pharmaceutical information to medical establishments in relation to the products and informing of any changes to the compounds of the products. A marketing office may be established in order to promote medical products and fulfil any MOH reporting obligations.

Additionally, there is now a prohibition on the pharmacist being able to substitute or replace prescribed pharmaceuticals, unless the relevant medical professional who issued the prescription is consulted. Breaches of the Law may result in fines for medical establishments of between 1,000 AED and 1,000,000 AED and or suspension, termination, or variation of its business licence. Imprisonment is also a possibility of between six months and five years, depending on the nature of the breach of this Law or repeated offences by an infringer.

DOH Telemedicine Standard

The DOH issued a new comprehensive telemedicine standard (the 'DOH Standard') on 16 September 2020, which governs telemedicine in Abu Dhabi. The DOH Standard permits telemedicine to be provided by healthcare physicians outside of the UAE and allows for specific tele-counselling collaborative partnerships to be entered into with DOH licensed healthcare facilities. The DOH Standard also permits physicians located outside the UAE to perform 'Tele-Medical Interventions', which are defined by the standard as "any interventive medical procedure that is taken remotely via information and telecommunication technologies". In accordance with section 10 of the DOH Standard, a physician based outside the UAE can enter into specific Tele-Medical Intervention collaborative partnerships with DOH tele-medical licensed healthcare facilities.

DHA General Circular No.9 of 2020, on Teleconsultation DSL Codes

The DHA issued an insurance circular establishing five new Dubai Service List ('DSL') codes for billing purposes to cater to teleconsultation services, with effect from 5 April 2020. The codes included those for teleconsultation with a general practitioner, specialist, consultant, allied health provider, and psychotherapy (psychologist), however, it does not include nursing consultations.

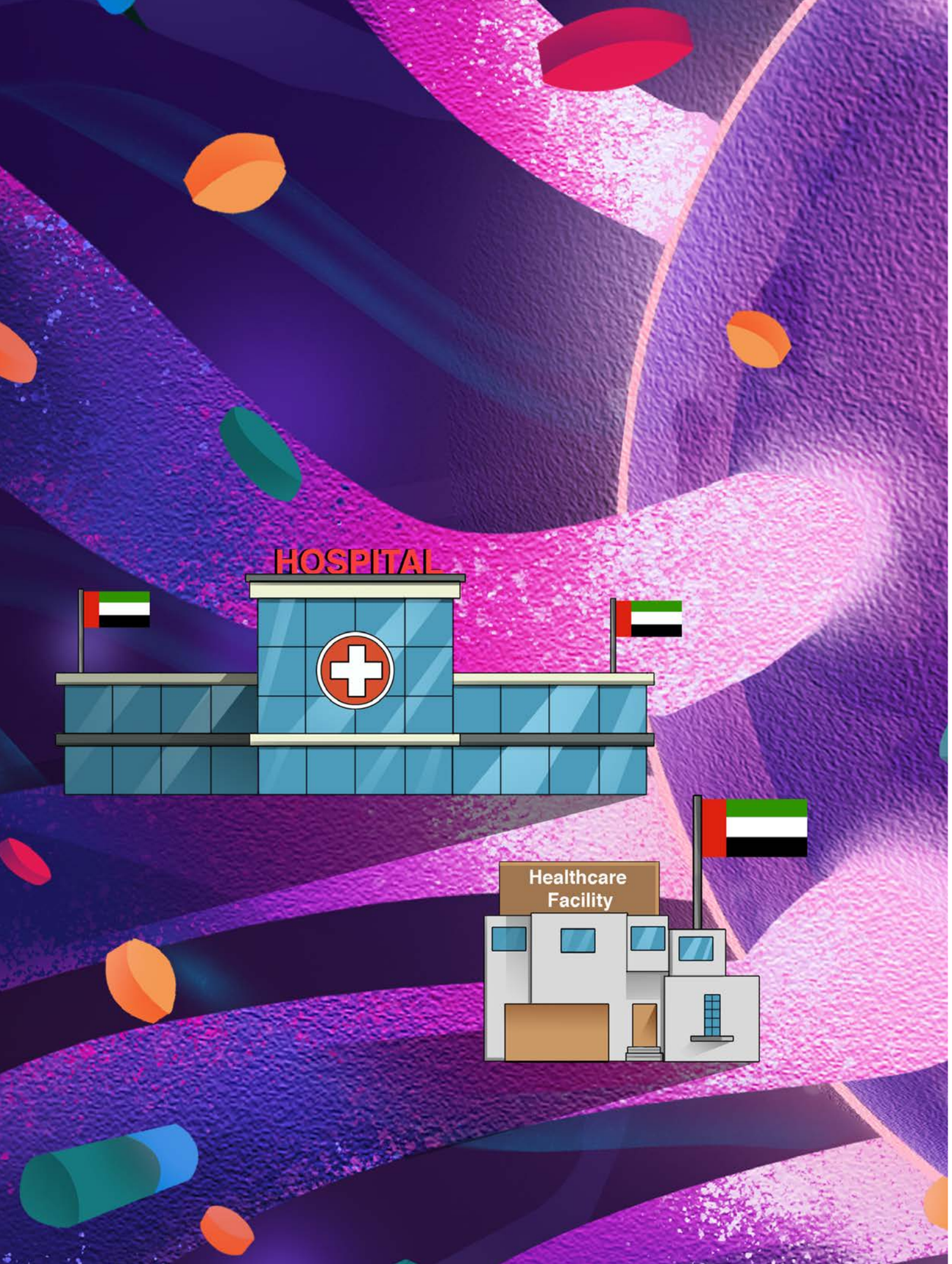
All categories of general practitioners, specialists, and consultants conducting teleconsultations will be covered in the respective codes. All service providers, insurers, and third party administrators are encouraged to begin discussions on pricing immediately. As per Policy Directive No. 2 of 2020, all payers must encourage and accept any claims, regardless of whether they had previously not agreed to telehealth services from the same network providers. To clarify, the directive does not mandate the default inclusion of any telehealth providers licensed by DHA that are not part of a payers' network; rather, the directive applies to those network providers with whom the payer has not extended telehealth services previously, which should now be included. The objective is to reduce unnecessary patient visits to medical facilities, where possible, during the COVID-19 pandemic.

Conclusion

Over the past few years, the healthcare sector in the Middle East has witnessed a rapid and significant overhaul of its regulatory frameworks as governments in the region issued new or enhanced laws and regulations, increased enforcement, and implemented programmes to attract private sector investment. This year has been no exception and, in some cases, has even been escalated by the COVID-19 pandemic.

Stay tuned; we expect 2021 to be an equally active year as the dust hopefully starts to settle from 2020.

For further information, please contact healthcare@tamimi.com.



Choosing suitable premises for your hospital or healthcare centre in Dubai and Abu Dhabi, UAE

David Bowman
Senior Counsel
Real Estate
d.bowman@tamimi.com

Christina Sochacki
Senior Associate
Corporate Commercial
c.sochacki@tamimi.com

DHA and DoH

While hospitals and healthcare centres outside free zones are governed by different authorities in Dubai and Abu Dhabi (the Dubai Health Authority ('DHA') and the Department of Health – Abu Dhabi ('DoH') respectively), the regulations in relation to the location and building type for a hospital or healthcare centre are quite similar in both Emirates, and are overlayed by federal laws, including the Federal Unified National Standards for Hopsitals of 2018 ('Federal Standard').

By way of background, the difference between a hospital and a healthcare centre, in both Dubai and Abu Dhabi, is determined on the services that will be provided. Generally, if inpatient services are provided, the operator must apply for a hospital licence; if not, then the operator must apply for a licence in their specialist area or areas.

Federal – Ministry of Health and Prevention

Under the Federal Standard, all hopitals in the UAE must be located in a freestanding facility, on a main road. Access to the building must be easy and convenient to people using both public transportation and private vehicles.

Dubai

The DHA guidelines stipulate the types of buildings that must be used for hospitals and healthcare centres, and lay down the further location and design requirements for these buildings, supplementing the Federal Standard.

Hospitals

As part of the licensing process the DHA will consider the plans for the premises and will also inspect the premises. If the premises do not meet the criteria set out in the Federal Standards and DHA guidelines, as well as the Dubai Universal Design Code and the Planning and Building sections of the Dubai Municipality, then the licence to operate will not be granted.

In both Dubai and Abu Dhabi, if a healthcare company wishes to establish a hospital, it must ensure that its premises are in an independent building. A healthcare centre however can be located in either an independent building or a villa; however, if a villa is to be used it must be converted from residential to commercial use.

Healthcare centres

Unlike a hospital, a healthcare centre, such as ambulatory care facilities, can have its premises at either an independent facility (such as a villa if it has been designated for commercial use), or in a mixed-use commercial building.

Abu Dhabi

Guidelines issued by the DoH (the 'DoH Guidelines') provide detailed information as to how different healthcare facilities are to be licensed. The DoH Guidelines also provide information as to how the hospital or healthcare centre should be designed and fitted-out. When applying to the DoH for a healthcare licence part of the application process involves an examination by DoH inspectors of the plans and drawings for the hospital or healthcare centre for compliance with the Federal Standard and DOH Guidelines (defined above). The DoH inspectors will assess the building and consider the fit-out design. Finally, the DoH inspectors will inspect the premises to ensure that the premises meets all the standards set out in the DoH Guidelines.

Hospitals

Similarly to the position in Dubai, a hospital in Abu Dhabi must have its premises in an independent building. Until several years ago, a hospital in Abu Dhabi could be located within a mixed-use building. Frequently such mixed-use buildings would contain residential apartments or commercial offices in addition to hospitals. The DoH now prohibits this.

Healthcare centres

Similar to the position in Dubai, a healthcare centre may use a villa as its premises, provided the villa has been granted permission to be converted from a residential villa to a villa allocated for commercial use. For such conversion to commercial use, it is necessary to obtain approval from the relevant local Municipality (there are three operating in Abu Dhabi: Abu Dhabi City Municipality, Al Ain City Municipality and Al Dhafra Municipality (the 'Municipalities')). Following the implementation in Abu Dhabi of Administrative Resolution No. 78 of 2020 (regarding permits to practise economic activities in buildings located in commercial hubs) ('Resolution No. 78'), the Municipalities may allow residential villas to be used for specific healthcare uses. Annex 3 to Resolution No. 78 lists various categories of healthcare activities that, with consent from the Municipalities, may in some cases be carried out from villas located in residential neighbourhoods. These villas must generally have a direct frontage onto a major street to enable easy access. If, after a detailed assessment, the Municipalities consider that the villas are suitable, they may be designated as commercial hubs ('Commercial Hubs'). Some permitted healthcare activities that may be carried out from Commercial Hubs, after consents are obtained, include: dental surgeries; paediatric clinics; cardiology clinics; diabetes clinics; physiotherapy centres; ophthalmology clinics; and care homes for the elderly or disabled. It is essential to bear in mind, however, that even if the Municipalities designated a residential villa as a Commercial Hub, approval would still be required from the DoH for the proposed healthcare activity. From our recent experience, the DoH maintains stringent requirements that must be satisfied before approving the use of a Commercial Hub for healthcare purposes. We, therefore, recommend that healthcare providers engage at an early stage with the relevant Municipality, and with the DoH, if planning to operate from a Commercial Hub.

Dubai Municipality ('DM') (and Trakhees for certain areas) is responsible for planning and zoning in Dubai. For each plot of land, DM issue an affection plan that shows the land plan and states the permitted use of it and any application for request to change the permitted use must be submitted to the Planning Department of DM. Once the application is approved, the DM charges a fee and issues an updated affection plan with the new usage.

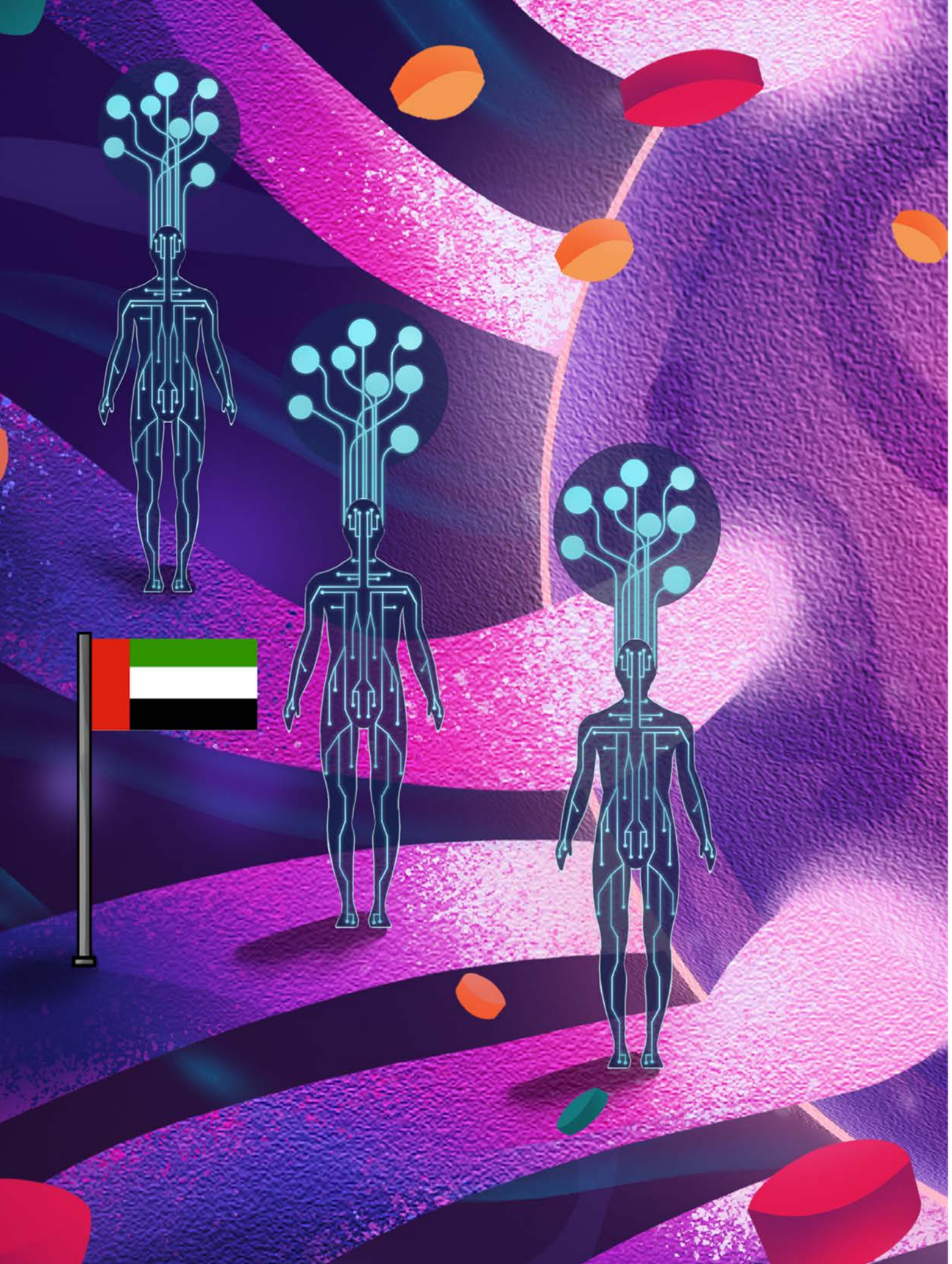
Naming a healthcare company

It is not permitted to have a company with the word 'hospital' in its name if the company will not be using the premises as a hospital. The Abu Dhabi Department of Economic Development requires that the activity of the company be reflected in the name; thus, if the facility is not licensed as a hospital, it can not use that term. Instead, it will need to state 'medical centre', for example, if its activity is that of a medical centre. This may mean that before applying for a commercial licence and approval as a medical facility, a company may need to change the name intended to be used. As the Department of Economic Development in both Abu Dhabi and Dubai have regulations in place that state that the name of the company should reflect the activity it is undertaking, it would be prudent for companies in Dubai to consider this as well.

Conclusion

In both Dubai and Abu Dhabi, if a healthcare company wishes to establish a hospital, it must ensure that its premises are in an independent building. A healthcare centre however can be located in either an independent building or a villa; however, if a villa is to be used it must be converted from residential to commercial use.

For further information, please contact healthcare@tamimi.com.



You are in my system: the implementing regulations on Federal law regulating the use of ICT in the UAE healthcare sector

Andrea Tithecott
Partner, Head of Healthcare and Regulatory
a.tithecott@tamimi.com

Andrew Fawcett
Senior Counsel
Technology, Media & Telecommunications
a.fawcett@tamimi.com

Last year, a federal law was issued to regulate the use of information communication technology ('ICT') in the healthcare sector through the United Arab Emirates ('UAE'), including in free zones (Federal Law No. 2 of 2019 ('ICT in Health Law')). While the ICT in Health Law came into force in May 2019, much of the key elements of the law were left to implementing regulations. At the core of the ICT in Health Law, it provided a basic framework, introducing a general prohibition on the transfer of health data outside the UAE and providing for the establishment of a central healthcare IT system ('Central System') for the purposes of collection, storing, and exchanging health data for all patients in the UAE. (Please see our summary of the ICT in Health Law, available here.

While further implementing regulations are still expected, in late April 2020, the Cabinet issued its first set of executive regulations to the ICT in Health Law (Cabinet Resolution No. 32 of 2020 ('ICT in Health Regulation'), which come into force in November 2020.

The ICT in Health Regulation has now specified the controls and protocols for the establishment, operation, and permitted access to the Central System. We outline the significant aspects of these below.

Joining the Central System (Art. 2)

Obligations required of health authorities and concerned entities joining the Central System include:

- compliance with the rules regulating the national registry;
- adherence to the deadline of joining the Central System; and
- payment of costs associated with connecting with the Central System.

Under the ICT in Health Law, 'concerned entities' include any authority or entity in the UAE providing health services, health insurance services, facilitation, claims management, electronic health services, or any entity directly or indirectly associated with the application of the ICT in Health Law.

The Ministry, in co-operation with health authorities and concerned entities, will also determine the procedures taken to ensure the quality of personal health data placed in the Central System.

The Ministry will also have the authority to audit any health data stored in the Central System to ensure the data's authenticity, quality, and its compliance with national digital health standards.

Establishment of a joint committee (Art. 3)

A new joint committee is to be formed by the Ministry, together with the health authorities and concerned entities; the aim of the committee is to govern the implementation of new joiners to the Central System.

Persons authorised and permission to access the Central System (Art. 4)

The health authorities and concerned entities have the authority to determine the persons authorised to access the Central System, as long as they meet certain safety and privacy standards set out by the Ministry.

Health authorities and the concerned entities must determine the persons authorised to access the Central System, on an as-needed basis, and depending on the professional role.

The Ministry (in co-ordination with other health agencies) is to establish the privacy and safety standards, and any controls to be adhered by the persons authorised to access the Central System.

Permission controls to use the Central System (Art.5)

No person may use the Central System unless authorised to do so by the health authorities or the concerned entities, in accordance with the following controls:

- a health authority will grant the permission to the following persons:
  - employees whose work requires the use of the Central System; and
  - persons who work through service outsourcing companies under contracts concluded with these companies, or experts and consultants who are hired on a casual basis, or the agencies and entities of the health authority. In all cases, the nature of their work or the tasks entrusted to them must require the use of the Central System.
- the health authority concerned will only grant the permission to the persons who work for it, provided that the nature of their work requires the use of the Central System, and the use must be within the limits of the actual need required by the work; and
- the health authority and the concerned entities will determine, as appropriate, the persons authorised to enter the Central System remotely.

Importantly for individuals, they may:

- give access to their personal health information to other persons of their choice, provided that such persons shall be registered as users in the Central System's database, in a manner that does not conflict with any other legislation issued in this regard; and
- request to prohibit or restrict access to their personal health information, in accordance with the requirements and controls set by the Ministry in co-ordination with other health authorities.

Conditions and controls for using the Central System and exchange of health data and information (Art. 6)

After obtaining permission, every person authorised to have access to the Central System has a duty of confidentiality to take all the necessary steps to protect the data and information in the Central System

In particular, in respect of a patient's data:

- the disclosure of the patient's health information to any party without the consent of the patient or his or her representative shall be legally prohibited, unless disclosure of this information is permitted in accordance with applicable law;
- in case of an emergency, and if the patient's consent cannot be obtained, healthcare providers may examine the patient's file for health care purposes;
- the consent of the patient should be obtained in the event of the publication of his or her identity data, and the list of the person's identity data shall be determined by a resolution of the Minister in co-ordination with the other health authorities; and
- all necessary steps should be taken to protect the patient's personal data and information from loss, misuse, unauthorised access, disclosure, modification, or destruction.

Controls for storing health data and information by means of information and communication technology (Art. 7)

Storing health data and information by means of ICT has to be according to specified controls including:

- the Central System should include all patient files in the UAE, and the files should contain data and information determined by the Ministry in co-ordination with other health authorities;
- a patient may choose to withdraw from the Central System: in such a case, data and information can be kept unidentified;
- health data and information that has exceeded the preservation period may be archived for research and public health purposes, while maintaining the patient's privacy (noting that the preservation period under the ICT in Health Law is 25 years);
- the Ministry, in co-ordination with health authorities, and through specialised committees, will set standards regarding the confidentiality, quality and validity of health data and information in a manner that does not violate UAE law but which reflects global standards; and
- health data and information should be stored by ICT means, and according to the regulations for maintaining medical records and archiving in force in each health facility, provided that it shall be compatible, at a minimum, with the controls set by the Ministry.

The Ministry, in conjunction with health authorities, is to issue the necessary decisions to implement the ICT in Health Regulation.

Summary

The ICT in Health Regulation prescribes controls and protocols necessary for the establishment and operation of the Central System including how it will be accessible to health authorities and other concerned entities in the health sector and the parameters on how the data can be used.

While the establishment of the Central System is a significant feature of the ICT in Health Law, it is not the only notable feature of the law.

Importantly, Article 13 of the ICT in Health Law provides that it is not permitted to store, develop, or transfer data and health information outside the UAE that is related to health services provided within the country, except in cases where a decree is issued by the health authority in co-ordination with the Ministry.

The ICT in Health Regulation is focused solely on the Central System and appears to be a preliminary guideline as further decisions are still needed by the Ministry and health authorities to implement them. We expect that further implementing regulations, or guidance at the emirate health authority level will be issued to detail further, for example, the process for a healthcare facility to join the Central System and the associated deadlines. Further, we are awaiting additional implementing regulations, or guidance from the individual emirate health authority level, to clarify the ICT Health Law's restriction on the transfer of health data outside the UAE and permissible exceptions.

For further information, please contact healthcare@tamimi.com.

Doctor influencer, are you ignoring the UAE rules?

Hey. Did you see the new post that influencer put up on that weight loss supplement? Look at her 'before' and 'afters', it can't be photo shopped. She said it works so it must! Who needs a gym and a nutritionist when the supplement makes you lose the weight and will make you look like her.

Influencer marketing has forever changed the world of marketing. In many ways, influencers rule the media industry ... and in doing so, they often flout the rules that apply in the advertising world.

Fiona Robertson
Senior Counsel,
Head of Media
f.robertson@tamimi.com

Minal Sapra
Paralegal
Technology, Media &
Telecommunications
m.sapra@tamimi.com

What's an influencer?

The 2018 Electronic Media Activity Regulation Resolution ('E-Media Law') was passed to address various categories on online commercial activity, and included regulations addressing the role of influencers. The E-Media Law does not include an express definition for an 'influencer'. Instead, it refers to the activities conducted online, which include: selling or otherwise dealing in print, video, and audio materials; electronic publishing activities and on-demand printing; specialised websites including news websites and online advertisements and applications; and any other electronic activity added in future by the National Media Council ('NMC').

It then goes on to note that:

"Any person who [undertakes these activities] on a commercial basis, shall obtain a prior license from the Council, provided that:

1. ...

2. Ads that are presented on Social Media shall be subject to the advertising standards that are applicable at the Council;

3. ...

4. The account owner is responsible for the content of the account."

The Article is clear. As you would expect, being online does not remove the obligation on the owner of an account from compliance with advertising standards.

The laws that govern social media and influencers

The Chairman of the Board's Resolution No. 26 of 2017 on Media Content ('2017 Resolution') was passed by the National Media Council to clarify the type of content that can be distributed in the UAE. Article 43 of the 2017 Resolution clearly states that "[a]ll paid advertising materials or items shall include a clear and candid indication that they are paid advertising materials or items." This applies to all media, including social media. In addition, Article 45(7) states that "the identity of the advertisement must be made clear and be presented as they are special and independent from the other advertising and editing materials or items, and borders must be placed to be separate such advertisement from any other material or item as well as intervals or time breaks in case of TV and radio broadcasting."

To help with the interpretation of these Articles in relation to social media and online advertising content, the government then issued Advertising Guidelines in 2018. These included the mandatory use of the hashtag '#ad' or '#paid_ad' for disclosure of the commercial relationship that is in place. These hashtags must be legible and easy to find – readers should not have to scroll down to find them. It is important to note that these are designed to protect consumers, and indicate to consumers that the influencer and the brand are both acting responsibly.

Specific rules for medical products

Article 45 of the 2017 Resolution notes that "[t]he prior consent must be obtained from the competent authorities in regards to whatever related to specialized advertisements such as those connected to medicine, medications".

So what does this entail, and does it apply to influencers?

The definition of Medical Product under Ministerial Resolution No. 430 of 2007, as amended ('Health Advertisement Resolution') is as follows:

"Everything works in or linked to the human health, such as medicine and drugs, including herbal medicine - health food, nutritional supplements and beauty centres - medical apparatus and supplies - medical institutions - people who [are] practicing medical profession of physicians and technicians - ways and methods of medical treatment by traditional or alternative methods."

This is a definition that is broad in scope and potential application. There is no doubt that it would include any product that claims to have a medical effect. If the claim is that a product will 'help you lose weight' or 'cure acne', this would be enough to trigger the application of the Health Advertisement Resolution.

A health advertisement, under that same Health Advertisement Resolution is noted as being:

"any information about the Medical Product in written, photographic and broadcasting form, in the form of a design, in the form of a product packaging in any of the media whether audio, visual and printed, in the form of posters in public places or in promotional form through the means of personal, technical or electronic messages communication."

This is also a broad definition. The Health Advertisement Resolution requires all such health advertising to be licensed before it is used within the UAE, when it will go through a rigorous approval process. The requirement for approval clearly extends to all forms of advertising and publicity, such as websites and social media and there is no indication in the Health Advertisement Resolution that it does not apply to influencers. On a strict interpretation of the law, influencers should only include content about a Medical Product within their social media feed if that content has been approved by the authorities.

The Health Advertisement Resolution requires all such health advertising to be licensed before it is used within the UAE, when it will go through a rigorous approval process. The requirement for approval clearly extends to all forms of advertising and publicity, such as websites and social media and there is no indication in the Health Advertisement Resolution that it does not apply to influencers.

The steps to take towards compliance

As long as:

1. the influencer has a licence;
2. the medical product is approved for use in the UAE;
3. the advertising material is approved under the Health Advertisement Resolution; and
4. the post has #ad included in the content,

then the parties involved should feel comfortable that they are compliant with the law. The authorities are not likely to ignore material that does not comply with the above; the health authorities, in particular, take this matter very seriously.

It really is no surprise that the authorities all expect influencers to comply with all laws that would apply to any entity that is undertaking advertising in the UAE. The surprise is the number of influencers who do not know about these laws or choose to ignore them.

For further information, please contact healthcare@tamimi.com.

A LEADER IN ECONOMIC & LEGAL REFORM: REMEMBERING THE LATE AMIR OF KUWAIT H.H. SHEIKH SABAH AL-AHMAD AL-JABER AL-SABAH

A Leader in economic & legal reform: remembering the late Amir of Kuwait H.H. Sheikh Sabah Al-Ahmad Al-Jaber Al-Sabah

Philip Kotsis
Partner, Co-Head of Office - Kuwait
Corporate Commercial
p.kotsis@tamimi.com

Lulwa Al Hammad
Associate
Corporate Commercial
l.alhammad@tamimi.com

A true Statesman, Humanitarian and Advocate for peace and unity

On 29 September 2020, the people of Kuwait learned of the death of their beloved Amir, H.H. Sheikh Sabah Al-Ahmad Al-Jaber Al-Sabah. Not only was the impact of his passing felt in the State of Kuwait, but also the world over, as the late Amir was a revered and respected statesman, humanitarian, and advocate for peace.

The late Amir, also known as the "Dean of Diplomacy" was able to position Kuwait in the eyes of the international community as a peacemaker, and a leader of a country that was focused on mutual co-operation and respect. Much of his success in making Kuwait a leader in this arena can be attributed to his 40 year tenure as Kuwait's Foreign Minister, a post he held prior to his succession to Amir in 2006.

His desire for diplomacy was evidenced in his role as a mediator in recent GCC disputes. The Late Amir was adamant in his belief of togetherness and co-operation amongst the six GCC countries, and stressed the importance of unity between the GCC to maintain global peace and security. This can also be demonstrated by the 2018 summit held in Kuwait to help rebuild and restructure Iraq, which resulted in billions of dollars of funding for Kuwait's neighbouring country. The Amir was also a key supporter in the recognition and support for Palestine wishing to see an end to the ongoing conflict.

Not only was the late Amir concerned with bridging and growing relations amongst the Gulf states, but it is clear that his humanitarian efforts had a worldwide impact as evidenced by the mourning seen in all corners of the globe. His Highness was a generous supporter of disaster relief and was constantly ensuring that donations, whether they be in the form of money or supplies, were sent to those in need which, in turn, has saved tens of thousands of lives worldwide.

The honours and awards granted to the late Amir are far from few, including the very recent Legion of Merit which was presented by U.S. President Donald Trump in recognition of his steadfast partnership with the United States. His Highness was honoured and his achievements were also recognised on numerous occasions by the United Nations, and in 2014, he was honoured by the United Nations as a "Humanitarian Leader," for his generous efforts in supporting humanity worldwide.

Leading Kuwait's surge in legal and economic reform

In parallel with his global accomplishments and in recognition of his humanitarian and peace efforts, the late Amir vaulted Kuwait forward on the domestic front with groundbreaking and forward thinking legal and economic plans and reforms.

During his leadership as Amir, Kuwait experienced a much needed and welcomed surge in legal reform that positively impacted, improved, and increased Kuwait's legal and regulatory regime across numerous governmental authorities and sectors. This not only included the reform of existing laws and the introduction of countless new ones, but also included the establishment of a number of governing authorities to provide oversight and regulation. These include authorities such as the Capital Markets Authority, Kuwait Direct Investment Promotion Authority, Kuwait Authority for Partnership Projects, Competition Protection Authority, and the Communication and Information Technology Regulatory Authority, to name just a few.

Along with the introduction and modernisation of new laws and regulations, the vision of His Highness to transform Kuwait into an international centre for commerce and industry by 2035 is already being implemented through Kuwait's National Development Plan.

The National Development Plan, based upon the vision of the late Amir, seeks to implement over 150 projects in the infrastructure, oil and gas, healthcare, transportation, electricity, housing, energy, and other sectors. Kuwait's commitment to building its infrastructure and expanding its oil sector projects was firmly set in motion under the late Amir, and based upon his vision, and the commencement of the National Development Plan, His Highness has not only raised the bar in terms of Kuwait's expectations moving forward, but has made possible countless opportunities for Kuwait companies, its citizens, and has widened the possibilities for foreign investors and investment within Kuwait.

A true Leader who will forever be remembered in our hearts

His mark as a true leader will not only be determined by the recognition of his efforts as a statesman, humanitarian, peace advocate, and not only for his strides in legal and economic reform but also in his ability to lead in times of adversity, and when a nation looks to its leader for strength and hope, that sets someone like the late Amir apart from others. The late Amir was revered for such accomplishments, which he carried out with dignity and respect. Kuwait will never forget the manner in which he carried himself and was seemingly able to embrace each and every individual within the borders of Kuwait. A perfect example of his ability to embrace and care for his nation was seen in his sincere and inspiring statements and actions in 2015 following the horrific bombing of a mosque in Kuwait City. The late Amir arrived on the scene within minutes of the tragedy, without any security arrangements, and declared "these are my children", a statement that will forever live on in the hearts of all citizens and residents of Kuwait.

The legacy of the late Amir, H.H. Sheikh Sabah Al-Ahmad Al-Jaber Al-Sabah, will continue to be remembered and carried out by the people of Kuwait, and the rest of the world. On behalf of Al Tamimi & Company we extend our most sincere and heartfelt condolences to the royal family and the people of Kuwait and offer our best wishes to Sheikh Nawaf Al Ahmad Al Jaber Al Sabah in his new role as Amir and Sheikh Meshal Al-Ahmed Al-Jaber Al-Sabah in his new role as the Crown Prince.

Development of Kuwait law

Alex Saleh
Partner, Co-Head of Office - Kuwait,
Head of Private Equity
Corporate Commercial
alex.saleh@tamimi.com

Arriving to Kuwait in 1994, I found the Kuwait legal system very archaic as we only really had three major laws: the Civil Code; the Commercial Law; and the old Companies Law. While providing advice was easy in the sense that we did not have a lot of legal authority to refer to, it clearly left substantial gaps in our ability to give clear and concise answers to various legal queries. The paucity of these laws were insufficient for the requirements of modern commerce and did not provide comfort for investors, whether foreign or local.

Fast forward to 2020 and the Kuwait legal landscape has gone through meteoric type changes. We have seen the rise of regulatory authorities where laws have been issued by Amiri decree or by parliament, which in turn established regulatory bodies that issued detailed executive regulations. The majority of the new legislation and the creation of these authorities to regulate the relevant laws have largely occurred in the decade between 2010 and 2020.

On the corporate side, our old companies law was antiquated and unable to deal with today's corporate vehicles. In 2012, and later amended in 2016, we witnessed the establishment of our new Companies Law. Instead of creating a separate authority, however, the Ministry of Commerce & Industry ('MOCI') issued the executive regulations and continues to regulate all corporate bodies in Kuwait. The new Companies Law has worked hand in hand with two other major corporate pieces of legalisation, the Capital Markets Authority ('CMA') Law, which was issued in 2010 and Kuwait Direct Investment Promotion Authority Law ('KDIPA'), which was issued in 2013. With the establishment of the CMA, we now had a regulatory body to supervise the promotion and sale of securities as well as licensing the various corporate bodies that were involved in the securities industry. In addition, given that Kuwait, like many of the GCC jurisdictions, has 51-49 per cent foreign ownership restrictions, the establishment of KDIPA, which provides licenses to foreign companies to be 100 per cent foreign owned, has given us the ability to bring in multi-national entities without the need for a local partner. A third major piece of legislation that is not corporate per se, but affects all mergers

This past decade has seen incredible growth in the development of Kuwait's legal system giving certainty to both local and foreign companies as they transact business within the state.

and acquisitions, was the Competition Protection Law, originally issued in 2007, but amended in 2012. With the establishment of Competition Protection Authority (the 'CPA'), we now had an ability to review and seek guidance from the CPA on any acquisitions that would affect competition in Kuwait.

On the project side, starting in 2008, but later completely amended in 2014, we saw the creation of the Public Private Partnership ('PPP') law and its regulatory body, the Kuwait Authority for Partnership Projects ('KAPP'). KAPP, which is responsible for our mega-projects, administers all PPP projects on behalf of all the relevant Kuwait ministries. New PPPs remain a top priority for the state, with the KAPP announcing several large-scale projects in different sectors, such as water generation, desalination and energy. Having represented major parties on various sides of PPP projects, including the government, sponsors, consortia and project finance lenders, we have had some slight challenges in the past; however, significant progress of PPP projects seems to be afoot. With respect to government bids conducted on the standard engineering, construction and procurement basis, Kuwait issued the Public Tenders Law in 2016, which also created the Central Agency for Public Tenders ('CAPT'). This new regulatory body regulates and administers all non-PPP projects.

Two industries that are traditionally heavily regulated in most jurisdictions, telecoms on the one hand and insurance on the other, have also been regulated in the State of Kuwait in the past few years. The Communications and Information Technology Regulatory Authority ('CITRA') was established in 2014 and is responsible for overseeing the telecommunications sector, monitoring and protecting the interests of users and service providers and regulating the services of telecommunications networks in Kuwait. On the insurance side, after a long delay, the new Insurance Regulation Law was issued in 2019 with the objective of establishing the Insurance Regulation Unit ('IRU') to regulate all types of insurance policies and insurance agencies.

Other notable laws and regulatory bodies established in the past decade include the Anti-Corruption Authority ('ACA') known locally as NAZAHA, which was established by law in 2016. NAZAHA was set up in response to the requirements of the United Nations Convention against Corruption ('UNCAC') which, in Article 6, stipulates that "each State Party shall, in accordance with the fundamental principles of its legal system, ensure the existence of a body or bodies, as appropriate, that prevent corruption."

The Consumer Protection Law which was established in 2014 creating the National Committee for Consumer Protection ('NCCP') to protect the interests of the Kuwait consumers and the Private Sector Labour Law of 2010 and the law establishing the Public Authority for Manpower ('PAM'), which was created to protect labourers employed in the State of Kuwait are also noteworthy.

The final big piece of legislation for this decade has just recently been issued,: the new Bankruptcy and Insolvency Law ('B&IL'), which is subject to its own article in this month's Law Update. We have waited years for bankruptcy reform as the current legal regime contained within the Commercial Law simply did not work. In addition to liquidation, we now have the ability to have preventive settlement and financial restructuring. More importantly, the B&IL will create specialised bankruptcy courts to oversee these types of cases. Two important agencies will also be created to streamline these cases. First, a Bankruptcy Commission will be established under the MOCI for certain companies, namely those regulated by the CMA, the Central Bank of Kuwait and State-owned entities. The Kuwait Judiciary will also establish a Bankruptcy Department for purposes of supervision of the insolvency proceedings.

This past decade has seen incredible growth in the development of Kuwait's legal system giving certainty to both local and foreign companies as they transact business within the state. The establishment of these authority bodies and the issuance of regulations strengthens business as it has: (i) enabled us to provide more certainty to clients with respect to their operations in Kuwait; (ii) with respect to new technologies, helps to create a market in Kuwait; and (iii) provided protection to the individual whether he or she is purchasing securities, consumer goods and/or his or her employment issues. We owe a debt of gratitude to the late Emir Sabah Al-Ahmad Al-Sabah, who oversaw this wonderful development of the Kuwait legal system. We are sure that these developments will pay dividends for future generations of Kuwait citizens and the country as a whole.

For further information, please contact Alex Saleh (alex.saleh@tamimi.com).

How COVID-19 is characterised under Kuwait Law

Philip Kotsis
Partner, Co-Head of Kuwait Office
Corporate Commercial
p.kotsis@tamimi.com

Ahmed Amin
Senior Associate
Corporate Commercial
a.amin@tamimi.com

Introduction

The COVID-19 pandemic has had a significant impact on businesses around the world, and Kuwait is no exception. Many Kuwait based contracts have been negatively affected by the COVID-19 pandemic, as contractors were unable to fulfil their obligations as a result of suspensions in their related industries and commercial sectors. This negative impact on businesses was also a result of unprecedented restrictions and precautionary measures implemented by the various governments around the world in an attempt to contain and combat the spread of COVID-19.

Major governmental and state-owned projects were negatively affected by the spread of COVID-19. Main contractors, as well as sub-contractors, were forced to claim variation orders due to the losses they incurred as a result of the protective measures imposed by the relevant authorities to combat the spread of COVID-19. The basis for such claims was founded on the theory that such measures represented a "change of law" in the construction industry. This is especially relevant in relation to contracts inspired by the FIDIC's model contracts, which entitles the main contractor and/or sub-contractor to claim damages from their employers where a change of law has been introduced, and which could not have been anticipated by any of the parties at the time of concluding the agreement.

Moreover, most of the contractual arrangements have been negatively impacted by the COVID-19, and in particular, contracts that depend heavily on time provisions as a major contractual element, such as lease contracts, supply contracts, and time or term performance deadlines.

How Kuwait has responded to the crisis

In Kuwait, the government took necessary and proactive measures to respond to the outbreak of the COVID-19 pandemic. Such measures were implemented on a gradual timetable to efficiently contain the pandemic, while at the same time, preserve the normal and smooth flow of the economy as best as possible. The measures contained the implementation of a lockdown, curfew,

suspension of inbound and outbound commercial flights, and suspension of certain businesses and commercial activities during the period from March through to August of this year.

Now, while many aspects of life and economic activity are back to normal, some contractual relationships continue to suffer the consequences and aftermath of the pandemic and its related measures that were required to be implemented by the official authorities.

Force Majeure and exceptional incidents under Kuwait law

COVID-19 may be interpreted as a foreign element which makes the performance of contractual obligations impossible or, if not impossible, onerous on the part of one, or both, of the contractual parties. The Kuwaiti Civil Code No. (67) of 1980 ('Civil Code') provides certain mechanisms to resolve the situation where one of the contracting parties is unable to perform its obligations under the contract due to a foreign element in which it played no part, and which negatively affects the performance of its obligations under the contract.

The Civil Code establishes two principles that tackle the foreign element and its impact on contractual relationships. These principles are:

1. force majeure, and
2. exceptional incidents.

These principles are codified to regulate contractual obligations where certain unexpected events arise that may affect the performance of contractual obligations under a contract.

Force Majeure

Prior to addressing the definition of force majeure under Kuwait law, it is important to understand that pursuant to the Civil Code, the contract itself determines the rights and obligations of the parties, and the same will neither be amended nor revoked except by the agreement of the parties or by a provision of the law. Therefore, the parties must first look to the agreed provisions in their contract to determine how to address exceptional event situations. In other words, the parties are required to first look to their contract to see if it regulates force majeure or related events. To the extent that the contract addresses the same, then the parties should apply these provisions accordingly. It is not uncommon for commercial contracts in Kuwait to contain a force majeure or hardship event clause, which, depending on the particulars of the agreement, could result in the termination of the contract, suspension of bilateral obligations temporarily, holding only the obligor liable for incurring the consequences of the unexpected event, or other agreed upon remedies.

Where a contract is silent in terms of force majeure, hardship, or other unexpected events, then assuming the contract is subject to Kuwait law, the relevant Civil Code provisions governing force majeure or exceptional incidents may apply.

Force majeure is defined under Article 215/1 of the Civil Code as "in bilateral contracts, where the performance of one of the parties' obligation becomes impossible due to an independent cause in which he played no part, the obligation becomes extinguished, and the corresponding obligation will be consequently extinguished and contract shall be, ipso facto, terminated."

Therefore, force majeure is an independent event where the cause cannot be attributed to the part or fault of any party to the contract and where such event makes the performance contract impossible.

Requirements to prove a case of Force Majeure

Unless there is an explicit agreement on the obligor's part to bear the consequences of a force majeure event, the Civil Code requires that a party prove certain conditions to be exempted from its obligation under the contract due to a force majeure event. These conditions are as follows:

1. the independent cause that represents the force majeure is unexpected. This means that none of the parties to the contract could have expected it when they initially concluded the agreement; or
2. the independent cause cannot be avoided and it makes the performance impossible.

As such, in addition to being unexpected, the party claiming the force majeure event must be able to show that it could not avoid the event and that its performance is impossible, and not merely inconvenient or burdensome. Conversely, if the situation can be avoided, or the relevant obligations are not impossible to perform, then the principle of force majeure should not be applied.

Consequences of claiming Force Majeure

As touched upon above, the Civil Code provides for the termination of the contract in the case of a force majeure event. Additionally, as a result of termination, the parties will be reinstated to the positions they were initially in prior to the conclusion of the contract. Moreover, unless there is an agreement to the contrary, the aggrieved party is not entitled to compensation if it is proven that the impossibility of performance is due to a foreign cause in which the obligor played no part. To this end, the Civil Code states that "where a person proves that damage has arisen by a cause beyond its control such as force majeure, unforeseen incident or the fault of the victim or a third party, such person shall not be liable for the damages, unless agreed to the contrary."

As the Civil Code suggests, it is permissible for the parties to agree in the contract that an obligor is responsible for the consequences of a force majeure event.

In light of the above, and given that COVID-19 is likely to be seen as an unexpected event, where a claimant is able to prove that COVID-19 has made the performance of his or her contractual obligation impossible, and where there is no provision in the agreement to the contrary, then the contract may be terminated in accordance with the Civil Code due to the occurrence of a force majeure event.

Finally, the effectiveness and mechanism for a termination of a Kuwait law governed contract also depends on the language of the termination clause provided in the agreement. Again, the parties should look to the language of their termination provisions to determine the appropriate course of action, and where the agreement is silent as to termination rights, or where force majeure cannot be linked to a termination provision, then the terminating party may be required to seek a court order for purposes of effecting the termination.

Exceptional Incidents

As mentioned above, the exceptional incidents principle is provided for under the Civil Code to also address the occurrence of unexpected events during the life of a contractual relationship.

This principle allows a contracting party to suspend the performance of a contract or request the resetting of the economics of the contract (i.e. economic rights and obligations) where an exceptional incident exists that could not have been foreseen by the parties at the outset of the agreement. In order to suspend the performance of the contract under the exceptional incidents principle, and unlike force majeure, the obligor is not required to prove impossibility of performance, rather, it is sufficient for the obligor to show that the exceptional incident creates hardship and makes the performance onerous.

Article 198 of the Civil Code states that where, after the conclusion of the contract and before completing its performance, exceptional circumstances that could not have been expected at the outset of the contract arise, which make the fulfilment of the contractual obligation excessively onerous (although not impossible) in such a way as to threaten the obligor with exorbitant loss, the judge may, according to the circumstances and after taking into consideration the interests of both parties, reduce the obligation to a reasonable level by limiting its application or increasing its consideration. Furthermore, Article 198 states that any agreement to the contrary in the contract shall be considered void.

Therefore, the key distinction between exceptional incidents and force majeure rests upon whether the unexpected event creates a hardship on one or more of the parties or whether the event renders the

An overview of force majeure and exceptional incidents in Kuwait and the impact of COVID-19.

agreement or obligations therein impossible to perform. Moreover, the remedies offered under each principle differ significantly, from termination of the contract under force majeure, to reduction or alteration of the obligation to alleviate the hardship under exceptional incidents.

Requirements for proving Exceptional Incidents

In order for a contracting party to avail itself of the exceptional incidents principle, the party must prove the following:

1. there must be a period of future performance between the execution of the contract and the exceptional incident;
2. the exceptional incident must arise after the execution of the contract;
3. the exceptional incident must be unforeseeable and not predictable or expected; and
4. the exceptional incident must create a hardship in the performance of the obligation, and not render the performance impossible.

Again, the distinguishing factors between proving a case for force majeure and exceptional incidents are that under force majeure the execution of the obligation becomes impossible, and under an exceptional incident the obligation becomes onerous (or a hardship is created).

Relief available under Exceptional Incidents

Unlike force majeure, an incident which qualifies as an exceptional incident is, ipso facto, temporary in nature, which means that it does not make the performance of a contractual obligation perpetually impossible, but rather, it makes it onerous for a limited period of time. Therefore, under exceptional incidents termination of the contract is not an available remedy. However, the following relief may be applied by the judge:

1. temporarily suspend the performance of the contract until the incident ends, allowing the parties to resume performance thereafter;
2. increase the obligations of the non-claiming party to reasonably achieve an economic equilibrium between them; or
3. reasonably reduce the onerous obligation of the obligor.

As such, under the exceptional incidents principle, the court is granted the discretion to put the parties in a position that they would have been in had the exceptional incident not occurred or other otherwise provide relief to achieve an equitable balance between the obligations of the parties.

Assessing Exceptional Incidents

A Kuwait judge, is the competent authority to adjudicate claims and determine the existence, applicability, and relief available in relation to force majeure or exceptional incidents in Kuwait. The Kuwait courts will look to the Civil Code to address situations where an unexpected event has occurred, and which negatively affects the performance of the contract. The court will further rely on the principles embedded within the Civil Code to determine whether the unexpected event is a force majeure event that makes the performance of the contract or obligation impossible, or whether it is an exceptional incident, which renders the performance onerous on one party but does not entail termination of the whole contractual relationship.

Commercial responses to COVID-19 by the Kuwait legislature

As mentioned above, due to the COVID-19 pandemic, the majority of businesses and commercial activities were suspended upon the imposition of an official lockdown by the Kuwait government. From a legal perspective, parties to periodical contracts such as lease agreements were among those most affected by the lockdown.

The Kuwait legislature, in order not to lessen the negative impact on such affected individuals and companies, introduced certain amendments to various laws. For example, amendments were made to the Kuwait lease law in order to reset the equilibrium between the lessor's right to receive the rent and to protect the tenant from eviction due to non-payment of rent. In its rationale, the legislature did not consider the lockdown as a force majeure event, as it did not completely release the tenant from paying rent, but rather delayed the payment of the same.

Moreover, with respect to the rights of litigants before the Kuwait courts, the legislature introduced certain amendments to the Civil and Commercial Procedures Law whereby all hearings falling within the period from March 2020 through June 2020 were postponed and rescheduled to ensure that litigants were not harmed by the protective measures imposed by the government to contain the spread of COVID-19.

The above are just a few examples of how the Kuwait government implemented commercial responses to the crisis in order to lessen the burden placed on individuals and companies during the lockdown period due to the COVID-19 pandemic.

Conclusion

The characterisation of COVID-19 as a force majeure or an exceptional incident is a debatable topic under Kuwait law and will depend upon the specific circumstances surrounding each contractual arrangement and the effect that the event has on the rights and obligations of the parties thereto. The Kuwait courts reserve a well established discretionary power to assess the circumstances of each case in determining whether claims are force majeure or exceptional incidents as a result of COVID-19 and its effect on businesses and contractual relationships.

Although the end to this COVID-19 pandemic may still be far off, and business will certainly continue to be affected by it and the precautions put in place by the Kuwait government to halt its spread as best possible remain in place, the Kuwait Civil Code is well equipped to deal with the repercussions from a contractual perspective by providing parties with the potential relief offered through the principles of force majeure and/or exceptional incidents.

For further information, please contact Philip Kotsis (p.kotsis@tamimi.com) or Ahmed Amin (a.amin@tamimi.com).

Amendments to the Kuwait lease law

Philip Kotsis
Partner, Co-Head of Kuwait Office
Corporate Commercial
p.kotsis@tamimi.com

Lulwa Al Hammad
Associate
Corporate Commercial
l.alhammad@tamimi.com

Introduction

In a response to the COVID-19 crisis, and after several discussions by the Parliamentary Legislative Committee, Law No. 15 of 2020, amending some provisions of Law No. 35 of 1978, regarding real estate leasing ('RE Law') was issued.

The amendments were an inevitable attempt to mitigate the projected overflow of cases being filed with the Kuwait courts as a result of tenants' failures to fulfil their financial obligations under their respective lease agreements.

This article highlights the amendments to the RE Law and touches upon the statutory protections afforded under the same.

Key amendment concepts

The amendment provides that "in all cases, a ruling may not be issued to vacate a leased premises if the tenant fails to pay the rent during a period within which the Council of Ministers decides to suspend work in all public facilities of the state, in order to protect security, public peace, or public health". Furthermore, the court will have the discretion to determine the method of late rental payment by the tenant, on a case-by-case basis. In our view this is the paramount addition to the RE Law which will alleviate the pressures faced by tenants during the global pandemic.

The amendment further stipulates that "in cases that deal with rents owed during the period that the Council of Ministers suspends activities to protect public health, then the period of suspension is not calculated within the dates stipulated in this law, provided that its calculation is resumed with effect from the day the Council of Ministers allowed work to return."

In other words, this will not be a rent free period, however, the payment of rent will be altered in a way so as to ensure that the landlord receives all money owed under the agreement and the tenant is able to make such payments in a way which will not compromise his/her standard of living, taking into consideration that many individuals' jobs have been impacted."

Furthermore, the amendment states that a single judge rental division will be established within the courts to be composed of one or more rooms as may be necessary. This new Division shall have sole jurisdiction to adjudicate the lease related disputes, irrespective of the value, and compensation arising therefrom. This is a welcomed departure from filing claims within the general court system and separating the same into specialised courts to deal with such landlord/tenant issues. This will not only alleviate the pressure on the general court system, but is expected to also allow the cases to receive specialist attention.

Implications of the new amendments

Pursuant to Article 10 of the RE Law the tenant must pay the rent in accordance with the written agreement. Without the passing of this amendment, landlords would have been entitled to file a case before the Kuwait courts to evict the tenant for failing to pay any rents due. Under the RE Law, a landlord's right to evict a tenant is limited to certain scenarios such as: (i) failure to pay rent as required, noting that it must be paid at the beginning of each month if the lease is monthly, or otherwise at the beginning of any contracted period for lease in other cases; (ii) if it is shown that the leased estate is prone to collapse and may expose the safety of tenants to danger, or should a resolution imposing demolition be issued by the competent town planning authority; (iii) If the residence is being used for illegal activities; or (iv) if the tenant subleased the leased estate or part thereof or assigned the lease contract to a third party without obtaining written consent of the landlord.

As such, the efforts of the legislature to protect tenants during the COVID-19 crisis, are evidenced in the new amendment, by providing relief to tenants from paying rent during these recognised suspended periods. Without the amendment, landlords could have put pressure on the tenants to pay all rents due and threatened eviction if the demands could not be met. Given the economic hardships brought about by the COVID-19 crisis such as loss of jobs, reduced wages, hiring freezes etc., the amendment has offered a much welcomed, and needed, haven for tenants during this difficult period, while at the same time accommodating the resumption of normal rental obligations after the suspension periods are lifted. In doing so, the rights of both the landlord and tenant are preserved, as the rent is not cancelled outright, but rather, the court will review each case brought before it and choose an appropriate mechanism of payment.

Additionally, the legislature has made an effort to speed up rental dispute procedures by implementing a system whereby a single judge will review the case as opposed to the previous system whereby the three judges formed the panel. This single judge together with the specialised court will be able to hear the disputes related to leases, regardless of their value, and potential compensation arising therefrom.

Key 'Things to Know' as a tenant

Rent increase: An important aspect of the RE Law, which remains unchanged by the amendment, is that it provides that the rent cannot be increased for a period of five years, from the date of signing the agreement. Once the lease expires, and where the rent is significantly less than the market price, then the landlord is permitted to increase the rent.

Notice period: The RE Law provides that a tenant must provide the landlord with his or her intent not to renew the lease: (i) 15 days prior to its expiration in the event that the lease duration is three months or less; (ii) one month prior in the event the lease duration is between three and six months; and (iii) two months where the duration of the lease exceeds six months. Notice should always be formally served in writing.

Given the economic hardships brought about by the COVID-19 crisis such as loss of jobs, reduced wages, hiring freezes etc., the amendment has provided a much welcomed, and needed, haven for tenants during this difficult period, while at the same time accommodating the resumption of normal rental obligations after the suspension periods are lifted. In doing so, the rights of both the landlord and tenant are preserved, as the rent is not cancelled outright, but rather, the court will review each case brought before it and choose an appropriate mechanism for payment.

Applicability on investment agreements

It is important to note that the RE Law does not extend to investment agreements, which are commonly used instruments by commercial premises owners, to aid them in avoiding the pro-tenant provisions of the RE Law. In an investment agreement, the contractual provisions will be upheld and will be read alongside the Civil Code and Commercial Law. A "lessee" will not benefit from the statutory protections offered to a lessee in a traditional lease agreement as detailed above. As mentioned, an investment agreement is commonly used in commercial settings and will generally contain intrinsic clauses which you would not traditionally find in a lease agreement.

For further information, please contact Philip Kotsis (p.kotsis@tamimi.com) or Lulwa Alhammad (l.alhammad@tamimi.com).

New Kuwait Bankruptcy Law

Akram Alzu'bi
Senior Associate
Banking & Finance
a.alzubi@tamimi.com

Law 71 of 2020 promulgating the bankruptcy law ('Bankruptcy Law') was published in the Official Gazette on 25 October 2020. It was approved by the Kuwait Parliament on 29 September 2020 and is aimed at increasing protection for troubled businesses and provides two new options to affected entities before they are forced to declare bankruptcy.

The Bankruptcy Law requires that the Minister of Commerce and Industry issue the Executive Regulation and Resolutions to apply the provisions of the Bankruptcy Law within six months of its publication in the Official Gazette. The Bankruptcy Law comes into force three months from the date such Executive Regulations are issued.

Historically, most corporate insolvencies in Kuwait have been resolved through consensual restructuring of the debtor company's liabilities, since market participants were reluctant to rely on legislation that was largely untested. The Bankruptcy Law is a major step forward and is influenced by features of a number of insolvency law regimes in other jurisdictions, as well as international insolvency law trends.

In general terms, the Bankruptcy Law streamlines and modernises Kuwait insolvency law and places a new emphasis on the early restructuring of indebtedness for distressed companies. A number of its features seek to destigmatise business failure and, therefore, it is to be hoped that it will serve as a catalyst for cultural change in the region that will ultimately lead to the promotion of a more robust legal framework for entrepreneurs and an improved climate for investors. Much will depend however, on how the Bankruptcy Law is used in practice and the willingness and ability of businesses and practitioners alike to adapt to take advantage of the legislative changes.

The new law does not treat failure to pay debt as a criminal offence, unless it is fraudulent. It also allows bankruptcy to be avoided either by a settlement with creditors or a restructuring plan.

The bankruptcy Law adopted the preventive settlement option

Scope of application

With the exception of joint venture companies and collective investment schemes, the Bankruptcy Law specifies the persons to whom the provisions of the law apply (which includes every natural person, trader, Kuwaiti companies and branches of foreign companies). The Bankruptcy Law gives the Central Bank of Kuwait and the Capital Markets Authority the right to set out rules governing preventive settlement procedures, restructuring and bankruptcy for stock exchanges, clearing agencies, central depository entities, central brokers, banks and insurance companies, in a manner that may deviate from the Bankruptcy Law and in accordance with the requirements of the nature of these entities.

The Bankruptcy Law provides for a Financial Restructuring Committee ('Committee') to be formed. The Committee's role is to oversee the management of restructuring procedures in order to facilitate consensual restructuring arrangements between a debtor and its creditors (where necessary) with the help of one or more Committee appointed experts. The Committee will also maintain a register of insolvencies, authorise expert fees and maintain an approved list of insolvency experts whose role is to assist the courts in assessing the grounds for, and implementing of, the chosen insolvency procedure (as described in more detail below).

Specialised bankruptcy court

For first time in Kuwait, a new specialised bankruptcy court has been established and the Bankruptcy Law provides that the judgments issued by the bankruptcy court shall be enforceable without declaration, and it is not permissible to dispute the judgments, and it is not permissible to suspend their implementation except in accordance with a ruling issued by the Court of Appeal.

The Bankruptcy Law states that the bankruptcy administration, within five working days from the date of the bankruptcy judge's decision, shall start the liquidation procedures, reject or accept the judgment, publish the decision and announce it, notify the concerned parties about it and disclose it on the Kuwait Stock Exchange if the debtor is listed, and instruct the debtor to disclose it on its website unless the bankruptcy judge decides that the other methods are sufficient.

Preventive settlement and financial restructuring

The Bankruptcy Law adopted the preventive settlement option to avoid insolvency by a debtor company in order to allow the discharge of debtor company's debts through an arrangement with the creditors called preventive settlement.

The bankruptcy court, based on a request by one of the affected creditors during the period following the decision to ratify the preventive settlement proposal and before the proposal is fully implemented, may order the termination of the preventive settlement procedures in the event of the conditions mentioned in the law being realised.

The preventive settlement proposal approved by the bankruptcy judge shall be enforceable against all the creditors including the creditors who rejected the proposal and those who did not attend the meeting re: voting on the proposal. The bankruptcy administration shall announce, publish, disclose and notify the commercial register in accordance with Article 31 of this law of every decision issued to ratify the preventive settlement proposal or to reject the proposal, suspend the ratification, terminate the procedures, open the restructuring procedures or declare bankruptcy within five working days from the date of issuance of the decision.

New specialised Bankruptcy Court has been established.

Penalties

The Bankruptcy Law increases the debtor's penalty from three years to five years and the fine from 30,000 (US$98,000) to 100,000 Kuwait Dinars (US$327,000) or one of these two penalties in the event of concealing the books or misappropriating part of the company's money. The chairman and members of the company's board of directors, its directors, the auditors of its accounts, and those in charge of liquidating shall be punished with imprisonment for a period not exceeding five years, and a fine not exceeding one hundred thousand Kuwaiti Dinars or either of these two penalties, if after the issuance of a final decision to open the bankruptcy procedures, they concealed the company's books or embezzled any of the bankrupt company's money.

For further information, please contact Omar Handoush (o.handoush@tamimi.com), Akram Alzu'bi (a.alzubi@tamimi.com) or Madhurima Basu (m.basu@tamimi.com).

Kuwait: considerations for guarantees

Madhurima Basu
Senior Associate
Banking & Finance
m.basu@tamimi.com

Ahmed Amin
Senior Associate
Corporate Commercial
a.amin@tamimi.com

Parties often rely on third party guarantees provided by companies and individuals for third part debts as a form of security or credit enhancement. While such corporate and personal guarantees provide some comfort to the creditor, there are various issues a creditor should be aware of to avoid pitfalls.

In Kuwait, the relevant provisions governing guarantees are set out in Law No. 67 of 1980 concerning enactment of the civil code 'Civil Code'. A guarantee, according to Article 745 of the Civil Code, is a contract between the guarantor and the creditor

"where a person joins his liability with that of the debtor in the performance of an obligation on him by undertaking to the creditor to discharge it should the debtor fail to do so".

Therefore, the guarantor's liability may be considered joint with the debtor. A guarantee may not be presumed and the consent of the surety must be express and accordingly, should be in writing.

Guaranteeing future obligations

Where a future obligation is being guaranteed, the maximum limit of the guarantor's obligations and the duration of the guarantee should be specified so that the guarantor may not back out of its responsibilities under the guarantee. There is no limit set out in the Civil Code regarding the guaranteed amount limit or the duration. However, according to Article 751 of the Civil Code and as confirmed by the Kuwait Court of Cassation in its decision no. 58 of 1985, hearing session dated 22 January 1986, a guarantee shall not be of a sum greater than the debt due from the debtor or have more stringent conditions.

Key issues in guarantees

The Civil Code sets out, among others:

- the guarantee is not valid unless the underlying obligation being guaranteed is valid;
- the liability of a guarantor is discharged if the debtor's obligations are discharged;
- if the guarantor has served notice on the creditor to initiate proceedings against

the debtor, the creditor has three months to initiate such proceedings failing which the guarantor can walk away from its obligations under the guarantee;

- the creditor must first exhaust its remedies against the primary obligor before taking enforcement measures against the guarantor in accordance with Article 760 of the Civil Code. However, Article 760 would not apply if the primary obligor and the debtor are said to be jointly liable for the debt or if the debt is a commercial debt; and
- if the principal obligor becomes bankrupt, the creditor must prove its debt (which it is owed) in the bankruptcy. Failing this, the creditor will lose its right to claim against the guarantor to the extent of any sums the creditor might have received had it proved the debt in the bankruptcy.

Demand under a guarantee

Unless the parties to a guarantee agree to submit their dispute to an amicable dispute resolution forum such as arbitration, the procedure to demand a guarantee under Kuwait Law includes, but is not limited to, serving a demand notice to both the guarantor and debtor (if applicable) to claim the amount of debt. If such amount is not paid by either the guarantor or the debtor, the creditor may file a lawsuit before the competent Kuwait court asking the court to oblige the guarantor to pay the debt. If the guarantee relates to a commercial debt, Article 99 of Law No. 68 of 1980 concerning the commercial laws sets out that the guarantors are jointly liable and the debtor and the creditor have an option of claiming its debt from whatever party.

Moreover, the lawsuit application shall be submitted by the creditor or a person legally authorised by the creditor, such as its lawyer. The court requests the creditor to pay the applicable court filing fees which are calculated based on the claimed amount. The court schedules a hearing session and notifies the respondents of the hearing.

While such corporate and personal guarantees provide some comfort to the creditor, there are various issues a creditor should be aware of to avoid pitfalls

Corporate benefit and authorisations

The concept of corporate benefit is not specifically included in Kuwait law. However, the provision of third party guarantees needs specific approvals from various types of Kuwait companies and is not considered ordinary course of business. If proper corporate authorisation is not in place, such a guarantee may be invalidated.

If authority cannot be established, a creditor may rely on the ostensible authority argument under the Civil Code. However, establishing the ostensible authority argument and piercing the veil between the company and the act made by an unauthorised person, is subject to the sole discretion of the court or tribunal in light of the circumstances, facts and documents presented by the parties to the dispute.

Due diligence of the guarantor's assets

While it is necessary to consider the legal issues set out above to avoid pitfalls, there is no substitute to conducting due diligence prior to the execution of a guarantee in respect of the nature of the guarantor's assets. Moreover, creditors should undertake periodic monitoring of the guarantor's assets as the provision of a guarantee does not prevent a guarantor from encumbering or disposing of their assets which has a practical effect on the value that may be placed on the guarantee.

It is important to note that Kuwait law does not recognise the concept of 'self-help remedies'. As such, guarantees in Kuwait must be enforced through a process led by the Kuwait courts and a creditor will require a court order to recover amounts due under a guarantee. In this context, conducting due diligence and identifying the guarantor's unencumbered assets assist the court in an expedient issuance of the attachment order and such order will prevent the sale of such assets pending the final judgment.

Conclusion

While there are various factors to consider before relying on a guarantee, guarantees can be helpful in enhancing the credit package of a transaction. Parties should consult with their legal counsel on the nuances of each situation to confirm the efficacy and suitability of a guarantee.

For further information, please contact Omar Handoush (o.handoush@tamimi.com) or Madhurima Basu (m.basu@tamimi.com).

16 NOV

Doing business in the region

In the month of The IBA Virtually Together Conference, we hosted an insightful webinar on doing business in the UAE, Egypt & KSA on Tuesday 16th November with Samer Qudah, Ayman Nour & Hesham Al Homoud as speakers and Ibtissem Lassoued as the moderator. Various topics were discussed including but not limited to the opportunities and recent developments for foreign investment in the UAE, Saudi Arabia's 2030 Vision, the growth of Egypt's GDP, and how the MENA region is supporting start-ups and SMEs as well as the challenges they regularly face.

Speakers: Samer Qudah, Ayman Nour, Hesham Al Homoud and Ibtissem Lassoued

16-17 NOV

Dubai Arbitration Week

Day 1 of Dubai Arbitration Week this year, @Dr Hassan Arab and @Sara Aranjo spoke at the event organized by the @International Chamber of Commerce "What's new in the new ICC Arbitration Rules 2021?

The 17th November was a busy day, @Dr Hassan Arab spoke at the ICC UAE Book Launch-Launch of ICC Publication: A Guide to Arbitration in the UAE. @Dr Hassan Arab spoke again alongside @Thomas Snider on the 'Techniques, Tips and Strategies for the Effective Management of International Construction Disputes' organised by @SIAC whilst @Sara Aranjo discussed 'Arbitration in Times of Pandemic' - organised by @ Herbert Smith Freehills, @Arbitration Pledge and @ArbitralWomen.

On Wednesday, 18 November 2020 @Sara Aranjo spoke at the Dubai Arbitration Week 2020 conference on the 'Common misconceptions of common law practitioners in MENA arbitrations' organized @Global Arbitration Review (GAR) and @DIFC-LCIA Arbitration Centre;

Finally, our arbitration team finished the week with our own virtual networking event which was a great opportunity for the community to reconnect, greet some familiar faces and welcome and meet new ones.

Although DAW looked different this year, we were still able to virtually connect with the Arbitration community and we look forward to 2021, hopefully in person!

Missed a webinar? View our webinar recordings on-demand on our YouTube channel!

2nd November
Private Client Solutions with RAK ICC Foundations
Speaker: Richard Catling

The Abraham Accords: The Genesis of a New Economic Chapter
Speaker: Essam Al Tamimi

3rd November
Speaking Opportunity
Plant fiction? Marketing plant-based substitutes for 'traditional milk' and meat products: cheese-free, beef-free cheeseburgers
Speaker: Fiona Robertson

Practical Insights for the development of the legal profession (Lecture for Emirates University)
Speaker: Essam Al Tamimi

4th November
The Implementation of VAT in Oman
Speakers: Shiraz Khan, Ahmed Al Barwani

Speaking Opportunity for Law Firm
Management Committee (IBA 2020)
How to be a successful and sustainable small/ medium size law firm
Speaker: Foutoun Hajjar

10th November
Joint webinar with DIFC
DIFC Intellectual Property (IP) Law
Speakers: Omar Obeidat, Ahmad Saleh and Rasha Al Ardah

11th November
Innovation & Efficiency Group GC roundtable
Speakers: Allison Hosking, Martin Hayward and guest speaker, Catherine Bamford.

Speaking Opportunity
Around the Globe with BHHS Georgia Properties webinar series
Speaker: Samer Qudah

23rd November
Virtual Managing Partners Forum

24th November
The Merits and Trials of Change: The truth about transforming court systems and legal practice based on experiences from around the world
Speakers: Essam Al Tamimi and Ibtissem Lassoued

29th November
Litigation Exclusive Forum – New Movable Security Law
Speakers: Naief Yahia, Stephany Malhame and Sarah El Serafy

8th December
She Breaks the Law – UAE- India special
#virtualevent

8th December
In conversation with Al Tamimi & Company: Roadmap to IPO and the Nasdaq Dubai Growth Market for SMEs
Speakers: Andrew Tarbuck and Anna Robinson

15th December
Legal Protection of Medical Research & Innovation
Speaker: Ahmad Saleh

About Us

Al Tamimi & Company has unrivalled experience, having operated in the region for over 30 years. Our lawyers combine international experience and qualifications with expert regional knowledge and understanding.

We are a full-service firm, specialising in advising and supporting major international corporations, banks and financial institutions, government organisations and local, regional and international companies. Our main areas of expertise include arbitration & litigation, banking & finance, corporate & commercial, intellectual property, real estate, construction & infrastructure, and technology, media & telecommunications. Our lawyers provide quality legal advice and support to clients across all of our practice areas.

Our business and regional footprint continues to grow, and we seek to expand further in line with our commitment to meet the needs of clients doing business across the Middle East & North Africa.

17	9	73	350+
Offices	Countries	Partners	Lawyers
450+	**850+**	**50+**	**1**
Legal Professionals	Employees	Nationalities	Fully Integrated Law Firm

Client Services

Practices

Arbitration • Banking & Finance • Capital Markets • Commercial • Competition • Construction & Infrastructure • Corporate/M&A • Corporate Services • Corporate Structuring • Employment & Incentives • Family Business • Financial Crime • Insurance • Intellectual Property • International Litigation Group • Legislative Drafting • Litigation • Mediation • Private Client Services • Private Equity • Private Notary • Projects • Real Estate • Regulatory • Tax • Technology, Media & Telecommunications •

Sectors

Automotive • Aviation • Education • Expo 2020 • FMCG • Healthcare • Hotels & Leisure • Rail • Shipping • Sports & Events Management • Transport & Logistics •

Country Groups

China • India • Korea • Russia & CIS • Turkey •

Publications

Al Tamimi & Company is at the forefront of sharing knowledge and insights with publications such as Law Update, our monthly magazine that provides the latest legal news and developments, and our "*Doing Business*" and "*Setting Up*" books, which have proven to be valuable resources for companies looking to do business in the region. You can find these resources at www.tamimi.com.

Accolades

Regional Footprint

Bahrain
Manama

Egypt
Cairo

Iraq
Baghdad
Erbil

Jordan
Amman

Kuwait
Kuwait City

Oman
Muscat

Qatar
Doha

Saudi Arabia
Al Khobar
Jeddah
Riyadh

UAE
Abu Dhabi
Dubai, DIC
Dubai, DIFC
Dubai, Maze Tower
Ras Al Khaimah
Sharjah

Key Contacts

CHAIRMAN
Essam Al Tamimi
e.tamimi@tamimi.com

MANAGING PARTNER
Samer Qudah
s.qudah@tamimi.com

SENIOR PARTNER
Husam Hourani
h.hourani@tamimi.com

Offices

BAHRAIN
MANAMA
Foutoun Hajjar
f.hajjar@tamimi.com

EGYPT
CAIRO
Ayman Nour
a.nour@tamimi.com

IRAQ
BAGHDAD
Mohammed Norri
m.norri@tamimi.com

ERBIL
Khaled Saqqaf
k.saqqaf@tamimi.com

JORDAN
AMMAN
Khaled Saqqaf
k.saqqaf@tamimi.com

KUWAIT
KUWAIT CITY
Alex Saleh
alex.saleh@tamimi.com

Philip Kotsis
p.kotsis@tamimi.com

OMAN
MUSCAT
Ahmed Al Barwani
a.albarwani@tamimi.com

QATAR
DOHA
Matthew Heaton
m.heaton@tamimi.com

SAUDI ARABIA
AL KHOBAR
Grahame Nelson
g.nelson@tamimi.com

JEDDAH
Ahmed Basrawi
a.basrawi@tamimi.com

RIYADH
Abdullah Mutawi
a.mutawi@tamimi.com

UAE
ABU DHABI
Alex Ghazi
alex.ghazi@tamimi.com

DUBAI, DIC
Ehab Morcos
e.morcos@tamimi.com

DUBAI, DIFC
Husam Hourani
h.hourani@tamimi.com

DUBAI, THE MAZE TOWER
Bassem El Dine
b.dine@tamimi.com

RAS AL KHAIMAH
Ammar Haykal
a.haykal@tamimi.com

SHARJAH
Zafer Oghli
z.oghli@tamimi.com

Practices

ARBITRATION
Thomas Snider
t.snider@tamimi.com

BANKING & FINANCE
Jody Waugh
j.waugh@tamimi.com

CAPITAL MARKETS
Andrew Tarbuck
a.tarbuck@tamimi.com

COMMERCIAL
Willem Steenkamp
w.steenkamp@tamimi.com

COMPETITION
Omar Obeidat
o.obeidat@tamimi.com

CONSTRUCTION & INFRASTRUCTURE
Euan Lloyd
e.lloyd@tamimi.com

CORPORATE/M&A
Abdullah Mutawi
a.mutawi@tamimi.com

CORPORATE SERVICES
Izabella Szadkowska
i.szadkowska@tamimi.com

CORPORATE STRUCTURING
Samer Qudah
s.qudah@tamimi.com

EMPLOYMENT & INCENTIVES
Samir Kantaria
s.kantaria@tamimi.com

FAMILY BUSINESS
Richard Catling
r.catling@tamimi.com

Nawal Abdel Hadi
n.abdelhadi@tamimi.com

FINANCIAL CRIME
Khalid Al Hamrani
k.hamrani@tamimi.com

INSURANCE
Yazan Al Saoudi
y.saoudi@tamimi.com

INTELLECTUAL PROPERTY
Omar Obeidat
o.obeidat@tamimi.com

INTERNATIONAL LITIGATION GROUP
Rita Jaballah
r.jaballah@tamimi.com

LEGISLATIVE DRAFTING
Mohamed Al Marzouqi
m.almarzouqi@tamimi.com

LITIGATION
Hussain Eisa Al Shiri
h.shiri@tamimi.com

PRIVATE CLIENT SERVICES
Essam Al Tamimi
e.tamimi@tamimi.com

PRIVATE EQUITY
Alex Saleh
alex.saleh@tamimi.com

PRIVATE NOTARY
Taiba Al Safar
t.alsafar@tamimi.com

PROJECTS
Mark Brown
m.brown@tamimi.com

REAL ESTATE
Tara Marlow
t.marlow@tamimi.com

REGULATORY
Andrea Tithecott
a.tithecott@tamimi.com

TAX
Shiraz Khan
s.khan@tamimi.com

TECHNOLOGY, MEDIA & TELECOMMUNICATIONS
Martin Hayward
m.hayward@tamimi.com

Sectors

AUTOMOTIVE
Samir Kantaria
s.kantaria@tamimi.com

AVIATION
Yazan Al Saoudi
y.saoudi@tamimi.com

EDUCATION
Ivor McGettigan
i.mcgettigan@tamimi.com

EXPO 2020
Steve Bainbridge
s.bainbridge@tamimi.com

FMCG
Samer Qudah
s.qudah@tamimi.com

HEALTHCARE
Andrea Tithecott
a.tithecott@tamimi.com

HOTELS & LEISURE
Tara Marlow
t.marlow@tamimi.com

RAIL
Foutoun Hajjar
f.hajjar@tamimi.com

SHIPPING
Omar Omar
o.omar@tamimi.com

SPORTS & EVENTS MANAGEMENT
Steve Bainbridge
s.bainbridge@tamimi.com

TRANSPORT & LOGISTICS
Yazan Al Saoudi
y.saoudi@tamimi.com

Country Groups

CHINA
Jody Waugh
j.waugh@tamimi.com

INDIA
Samir Kantaria
s.kantaria@tamimi.com

KOREA
Omar Omar
o.omar@tamimi.com

RUSSIA & CIS
Matthew Heaton
m.heaton@tamimi.com

TURKEY
Omar Obeidat
o.obeidat@tamimi.com

“We appreciate the diversity of the lawyers’ backgrounds – there’s always someone qualified to answer any query.

Chambers Global

Contact Us

BAHRAIN

Manama Bahrain Financial Harbour, West Tower, 13th floor, Suite 1304, Office 13B, Building 1459, Block 346, Manama, Bahrain

T: +973 17 108 919 / F: +973 17 104 776

EGYPT

Cairo Building No. 5&7 (Star Capital Building), 10th Floor, Geziret El Arab Street, Mohandseen, Giza, Cairo, Egypt

T: +20 2 3368 1000 / F: +20 2 3368 1002

Al Tamimi & Company is associated with Nour & Partners providing legal services in Egypt.

IRAQ

Baghdad Al Harithiya, Kindi St., Dist. 213 Building 106, 1st Floor, Baghdad, Iraq

T: +964 780 029 2929 / F: +964 1 542 0598

Erbil English Village, Gulan Street, Villa No. 130, Erbil, Iraq

T: +964 780 588 7848 / F: +964 750 445 2154

Basra info@tamimi.com.

JORDAN

Amman 6th Circle, Emmar Towers, 11th Floor, Tower B, PO Box 18055, Zip 11195, Amman, Jordan

T: +962 6 577 7415 / F: +962 6 577 7425

KUWAIT

Kuwait City Khaled Bin Al Waleed Street, Sharq, Al Dhow Tower, 16th Floor, PO Box 29551, Safat 13156, Kuwait City, Kuwait

T: +965 2 225 3700 / F: +965 2 296 6424

Al Tamimi & Company in association with Omar Khaled Al-Qahtani provides legal services in Kuwait.

OMAN

Muscat Al Assalah Towers, Building 223, Block 237, Office 409, Street 3701, Ghubrah South, Muscat, Oman

T: +968 2421 8554 / F: +968 2421 8553

Al Tamimi, Al Barwani & Co. is trading under the registered trade mark of "Al Tamimi & Company".

QATAR

Doha Tornado Tower, 19th Floor Majlis Al Taawon Street, PO Box 23443, West Bay, Doha, Qatar

T: +974 4457 2777 / F: +974 4360 921

Adv. Mohammed Al-Marri in association with Al Tamimi & Company.

SAUDI ARABIA

Al Khobar 9th Floor, Zamil House Prince Turkey Street, Corniche District, PO Box 32348, Al Khobar, Saudi Arabia 31952

T: +966 13 821 9960 / F: +966 13 821 9966

Jeddah King's Road Tower, 11th Floor, King Abdulaziz Road, Al Shate'a District, PO Box 9337, Jeddah, Saudi Arabia 21333

T: +966 12 263 8900 / F: +966 12 263 8901

Riyadh Sky Tower (North Tower), 9th Floor, King Fahad Road, Al Olaya District, PO Box 300400, Riyadh, Saudi Arabia 11372

T: +966 11 416 9666 / F: +966 11 416 9555

UNITED ARAB EMIRATES

Abu Dhabi Al Sila Tower, 26th Floor, Abu Dhabi Global Market Square, Al Maryah Island, PO Box 44046, Abu Dhabi, UAE

T: +971 2 813 0444 / F: +971 2 813 0445

Dubai Internet City T: +971 4 364 1641 / F: +971 4 3641 777

Dubai International Financial Centre 6th Floor, Building 4 East, Dubai International Financial Centre, Sheikh Zayed Road, PO Box 9275, Dubai, UAE

T: +971 4 364 1641 / F: +971 4 3641 777

Dubai Maze Tower Level 15, Sheikh Zayed Road, PO Box 9275, Dubai, UAE

T: +971 4 331 7161 / F: +971 4 331 3089

Ras Al Khaimah Julphar Office Tower, 39th Floor, Al Jissar Street, PO Box 34053, Ras Al Khaimah, UAE

T: +971 7 233 3841 / F: +971 7 233 3845

Sharjah Al Khan Corniche Street Near Al Qasba Canal 30th Floor, Al Hind Tower PO Box 5099, Sharjah, UAE

T: +971 6 572 7255 / F: +971 6 572 7258

For any queries, please email **info@tamimi.com.**

@AlTamimiCompany

Al Tamimi & Company

www.tamimi.com

التميمي و مشاركوه
AL TAMIMI & CO.