
CHAMBERS GLOBAL PRACTICE GUIDES

Life Sciences 2026

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UAE

Law and Practice

Haykel Hajjaji, Julie Teperow, Robin Blaney
and Winsome Cheung

Trends and Developments

Winsome Cheung and Haykel Hajjaji

Covington & Burling LLP





Law and Practice

Contributed by:

Haykel Hajjaji, Julie Teperow, Robin Blaney and Winsome Cheung
Covington & Burling LLP

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Covington & Burling LLP offers one of the world's largest and most comprehensive life sciences-focused practices. Its clients – spanning every sector and ranging from emerging biotech ventures to global pharmaceutical companies and major trade associations – trust the firm with their most complex business challenges. The firm has clients across the entire product life cycle, going well beyond traditional legal services to enable efficient R&D, successful launch and commercialisation, and long-term value maximisation. Covington supports numerous leading life sciences companies on strategic transactions,

M&A, financings, and emerging issues including digital health, post-Brexit regulatory divergence, privacy, innovation incentives, reimbursement, and evolving medical device and diagnostic regulations. It also guides clients through rapidly shifting political and policy landscapes, including drug-pricing initiatives and implications for compliance, trade, antitrust, and litigation. The team includes more than a hundred dedicated life sciences lawyers, many of whom previously held senior positions at regulatory agencies, major manufacturers, or industry associations.

Authors



Haykel Hajjaji is a partner at Covington & Burling LLP who advises global corporations, sovereign investors, and financial institutions on complex cross-border transactions, regulatory strategy, and market entry

across the Middle East. His practice spans corporate, M&A, and commercial advisory matters, with a focus on strategic expansion into the Gulf. Haykel has deep expertise at the intersection of innovation, regulation, and geopolitics, particularly across AI, data centres, life sciences, defence, supply chain, and infrastructure. With over two decades of experience, he counsels clients on market entry, transaction structuring, foreign investment regimes, and legal risk in sensitive environments.



Julie Teperow is a special counsel at Covington & Burling LLP who advises multinational clients on complex local and international regulatory, public policy, and corporate matters across sectors including life sciences,

technology, and consumer products. She has extensive experience in regional cross-border compliance, supporting clients as they navigate regulatory frameworks and the practical challenges of doing business in the Middle East and North Africa. Julie also advises on government affairs in the GCC, focusing on commercial, trade, and market access issues, and supports clients entering

emerging markets. In addition, she handles regulatory aspects of corporate and commercial transactions.



Robin Blaney is a partner at Covington & Burling LLP who advises pharmaceutical, biotechnology, and medical device companies on a broad range of regulatory, compliance, transactional, and legislative matters,

as well as commercial agreements spanning the full product life cycle. He regularly supports human and veterinary pharmaceutical companies on advertising and GxP issues, including clinical trials, pharmacovigilance, and manufacturing. Robin also advises on the regulatory aspects of M&A, licensing, and collaborative transactions, with significant experience in transitional regulatory, and supply arrangements. His commercial expertise includes clinical trial, manufacturing, and distribution agreements, and he has notable experience structuring international distribution and licensing frameworks.



Winsome Cheung is a partner at Covington & Burling LLP who represents global pharmaceutical and biotechnology companies on strategic partnering and collaboration arrangements. A former scientist with

a PhD in medicine, she draws on deep scientific and industry insight to advise clients across the life

sciences value chain. She leads major cross-border licensing and collaboration transactions, including high-value alliances, option agreements, and asset acquisitions. Winsome also advises on ecosystem-wide initiatives, including serving as a chief legal adviser to a global antiviral consortium, and long-term strategic partnerships in genomics. She regularly counsels investors and biotechnology companies on IP licensing, manufacturing, and commercial agreements.

Covington & Burling LLP

Office No. 703, Level 7
Gate Precinct Building 3
Dubai International Financial Centre
P.O. Box: 507082
Dubai
UAE

Tel: +971 4 247 2100
Email: CFoster@cov.com
Web: www.cov.com/en/

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1. Life Sciences Regulatory Framework

1.1 Legislation and Regulation

Pharmaceuticals and medical devices in the UAE are governed by Federal Decree-Law No 38 of 2024 Governing Medical Products, Pharmacists, and Pharmaceutical Establishments (“Pharma Law”). The Pharma Law refers to both pharmaceuticals and medical devices as “medical products”.

The Ministry of Health and Prevention (MOHAP) and the Emirates Drug Establishment (EDE) are the regulatory bodies that apply and enforce pharmaceutical and medical device regulation at a federal level.

MOHAP, as a UAE federal ministry, is part of a centralised administration, whereas EDE is a semi-autonomous regulator.

There are emirate-level regulators that issue regulations for their respective emirate as well:

- the Dubai Health Authority (DHA) in Dubai; and
- the Abu Dhabi Department of Health (DOH) in Abu Dhabi.

1.2 Challenging Decisions of Regulatory Bodies

Under the Pharma Law, certain decisions may be appealed. These include the rejection of an application for a pharmacist licence and any disciplinary penalty issued under the Pharma Law. Appeals must be filed within 15 days. The Pharma Law does not specify the detailed requirements or procedures for filing such appeals, which are expected to be clarified in the forthcoming Implementing Regulations (IR).

In addition, claimants may challenge certain decisions issued by MOHAP or the EDE. Specifically, MOHAP provides an appeal service for decisions issued by the Medical Licensing Committee and for previously recorded health advertisement violations.

For appeals against Medical Licensing Committee decisions, the required documentation includes an appeal letter addressed to the Minister of Health and Prevention, along with all documents relevant to the grievance. For appeals relating to previously recorded health advertisement violations, claimants must provide identification documents that substantiate the basis of the appeal.

These appeal procedures vary depending on the sector and the regulatory body involved. Each regulatory authority has its own requirements and processes for challenging decisions. It should also be noted that food supplements and cosmetics fall within the scope of the Pharma Law.

There is limited publicly available information on challenges to decisions by MOHAP and the EDE, and court cases in the UAE are generally not made public.

1.3 Categories of Pharmaceuticals and Medical Devices

Pharmaceuticals are regulated as:

- prescription only;
- pharmacy only (over-the-counter);
- controlled products (includes toxic substances and plants, narcotic and psychotropic substances, and hazardous medical products);
- innovative pharmaceutical products;
- orphan drugs;
- emergency-use medical products; and
- compassionate-use products.

Medical devices are regulated based on risk, similar to the FDA's Classes I–III. The medical devices' classification determines the permitted sales channels, regulating where and how a medical device may be sold.

2. Clinical Trials

2.1 Regulation of Clinical Trials

Clinical trials of medical products are regulated and overseen by the EDE. Their governance is largely based on the Good Clinical Practice (GCP) framework. The federal Guidelines for Conducting Clinical Trials with Investigational Products and Medical

Devices establish the relevant ethical and regulatory processes.

Under the Pharma Law, operating a clinical research entity requires obtaining a licence from the EDE. Among the key requirements for securing an EDE licence are as follows.

- Holding a valid GCP Certificate issued by the EDE.
- Demonstrating a GCP-compliant quality management system and maintaining written standard operating procedures.
- Ensuring that all data, including personal data of research participants, remains confidential.

The specific “terms, controls, and procedures” governing clinical research will be detailed in the forthcoming Implementing Regulations. Until those regulations are issued, the UAE continues to rely on the existing regulatory framework, which is grounded in the GCP standards.

Additionally, the DOH and DHA maintain their own clinical research guidelines for studies conducted within their respective emirates, complementing the federal framework.

- Department of Health – its guidelines adopt GCP as the core standard, emphasising credible data; the protection of trial subjects' rights, integrity, and confidentiality; and detailed requirements regarding ethics/research committees, trial authorisation, and safety reporting obligations.
- Dubai Health Authority – under the DHA Clinical Trials Policy, GCP is also adopted as the fundamental standard, with a focus on safeguarding participants' rights, safety, welfare, and data confidentiality. The Dubai Scientific Research Ethics Committee and the DHA Medical Education and Research Department serve as the centralised bodies for approvals and oversight, including mandatory ethical approval, facility authorisation, and adverse event reporting.

2.2 Securing Authorisation to Undertake a Clinical Trial

Under the Pharma Law, conducting clinical trials without first completing non-clinical research is prohibited,

except in cases involving the compassionate use of pharmaceuticals and medical devices.

For interventional clinical trials, approvals must be obtained from both the EDE and the Ethics Committee, and an import permit for the medical product is required.

For non-interventional clinical trials, approval from an Ethics Committee is necessary, and the EDE must be notified.

Clinical trials may also be conducted by submitting an application through the DHA or DoH.

2.3 Public Availability of the Conduct of a Clinical Trial

There is currently no comprehensive database for clinical trials in the UAE. However, the UAE has launched the UAE Health Research Portal (“Health Portal”), which provides access to data and information from clinical trials as well as health and biomedical research publications conducted in the UAE. It is not yet clear, though, whether the portal offers complete or fully comprehensive coverage of all such research activities.

2.4 Use of Online Tools to Support Clinical Trials

There are no restrictions for using online tools to support clinical trials in the UAE.

2.5 Use of Data From Clinical Trials

Health data in the UAE is governed by Federal Law No 2 of 2019 Concerning the Use of Information and Communications Technology in Health Fields (“Health Information Law”) and Ministerial Decision No 51 of 2021 (“Health Data Transfer Regulation”).

Under the Health Information Law, health data – including data resulting from clinical trials – must comply with the following requirements.

- Health data must be kept confidential and may not be shared unless permitted.
- Health data may not be stored, transferred, or processed outside the UAE.

- Any circulation or transfer of health data must preserve patient confidentiality and may only be used for health-related purposes unless the patient provides approval.

The Health Data Transfer Regulation outlines the circumstances under which health data may be stored or transferred outside the UAE as exceptions to the restrictions set out in the Health Information Law. One of these exceptions includes data used for approved scientific research.

Data transferred under the scientific research exception must be encrypted and anonymised, and it may only be used for the purposes of that specific scientific research. Such data may only be shared with the relevant entity.

In practice, approval from the health authority of the relevant emirate may be required before transferring health data.

Under the UAE Personal Data Protection Law (PDPL), biometric and health data (including genetic data and healthcare-related data) are considered sensitive personal data.

Under the PDPL, any transfer of personal data must rely on a lawful basis, one of which is consent.

Data necessary for scientific studies is listed as an exception under the PDPL, meaning it may be processed without consent. This exception, however, remains subject to the requirements of the Health Information Law and the Health Data Transfer Regulation.

Additionally, the Department of Health, under its Healthcare Data Privacy Standard, and the Dubai Health Authority, under its Policy for Health Data and Information Sharing, prohibit the transfer of patient health data unless expressly authorised by the DOH or DHA.

2.6 Personal or Sensitive Data

Personal and sensitive data will be subject to the PDPL, the Health Information Law, and the Health Data Transfer Regulation.

The Health Information Law stipulates that health data may not be used for purposes unrelated to healthcare without the patient's consent. However, scientific and clinical research is exempt from this consent requirement, provided that the patient's identity is not disclosed.

In addition, the Guidelines for Conducting Clinical Trials with Investigational Products and Medical Devices require that all information related to clinical testing must be recorded, monitored, processed, and stored in accordance with the PDPL and the Health Information Law.

3. Marketing Authorisations

3.1 Product Classification

Pharmaceutical products are products that contain one or more active substances that achieve their intended purpose in or on the human or animal body through a biological effect. They are manufactured, sold, or offered for use in the diagnosis, treatment, cure, alleviation, or prevention of disease, as well as the restoration, renewal, modification, or correction of organ functions.

Pharmaceutical products also include biological products, food supplements, and cosmetic products.

- Biological products are products obtained through biotechnology from a living organism. These include vaccines, monoclonal antibodies, growth factors, blood derivatives, plasma derivatives, advanced therapy medicinal products, and allergy diagnostic products.
- Food supplements are products taken orally to support the human diet. They have no role in the treatment, diagnosis, or prevention of diseases and consist of natural products, partially manufactured products, or both.
- Cosmetic products are products with a physiological effect that are used on the human body to produce a desired local effect on the skin, hair, or nails. They do not require a medical prescription or direct medical supervision when used.

Medical devices are products – whether a substance, device, instrument, appliance, implant, detector, or system, including accessories and operating software – that achieve their intended purpose in or on the human or animal body without a pharmacological, immunological, or metabolic effect. They are manufactured, sold, or offered for use in the diagnosis, treatment, cure, alleviation, monitoring, or prevention of a disease, injury, or disability; the detection of, compensation for, or modification of an anatomical condition; and the regulation of conception.

To obtain an official classification of a medical product, an application may be submitted to the EDE. The EDE will then issue a classification letter specifying the product's regulatory category.

3.2 Marketing Authorisation for Biologic Medicinal Products

There is a distinct Marketing Authorisation (MA) application process for biological products, which must be submitted through the EDE portal. Biological products are subject to additional requirements compared to other medical products.

To obtain an MA for a biological product, applications must be submitted in accordance with the eCTD format. This format requires extensive quality, clinical, and non-clinical data, including chemistry, manufacturing and controls (CMC) information, as well as non-clinical pharmacology, toxicology, and immunogenicity studies, among other elements.

A Good Manufacturing Practice (GMP) Certificate issued by the EDE, or an equivalent certificate from a reference jurisdiction accredited by the EDE, is also required.

Conditional Marketing Authorisation may be granted for biological products intended for the treatment of rare diseases, provided the product has received provisional approval from a recognised reference jurisdiction.

3.3 Period of Validity of Marketing Authorisations

Marketing Authorisations are valid for five years and may be renewed through the EDE Portal for an additional five years.

An MA may be revoked under any of the following circumstances.

- The medical product, if domestically manufactured, has not been placed on the market within two years; or, if imported, within one year.
- A medical product granted an Emergency Use Authorisation or a Conditional Marketing Authorisation has not been placed on the market within three months.
- The medical product has not been available on the market for two consecutive years after it was initially placed on the market.
- The MA was granted based on incorrect or misleading documents.
- A decision has been issued to prohibit the manufacture, distribution, or circulation of the medical product in either the UAE or any reference jurisdiction.
- It is proven that a Medical Products Factory or a Contract Manufacturing Organisation failed to comply with Good Manufacturing Practice (GMP) or Good Storage and Distribution Practice (GDP) in a manner that affects the quality of the medical product.
- The medical product is proven to be unsafe or has repeatedly failed to meet approved quality standards when tested by the EDE's Quality Control Laboratory.
- The medical product is found to be unsafe or unreliable due to new safety concerns, or due to reports of adverse reactions or adverse medical events that require its withdrawal.
- A decision has been issued prohibiting the activity of a Medical Products Factory, a Contract Manufacturing Organisation, a Medical Warehouse in the State, or of the entity represented by the Marketing Office in the country of origin or by any of the EDE's accredited reference authorities.

3.4 Procedure for Obtaining a Marketing Authorisation

An MA is obtained by applying to the EDE through its online portal, completing the application form, submitting the required documents, and paying the applicable fees. The applying entity must be registered with the EDE prior to registering its products.

The application requirements are as follows.

- A certificate of pharmaceutical product or a certificate of free sale issued by the country of origin and certified by the UAE Embassy. The certificate must include the product brand name, and the name and address of the marketing or manufacturing company.
- One sample of the product.
- A registration certificate of the manufacturing company issued by the EDE.
- A Halal certificate.
- A company statement confirming that the product is free of "hormones, heavy metals, antibiotics, steroids, pig derivatives, and any other natural or chemical substances that have a harmful impact on humans." If the product contains substances derived from animals, the type of animal and the part from which the substance is extracted must be specified. The statement must also include the percentage of alcohol used, if any, and the justification for its use.
- A certified copy of the contract between the marketing company and the local agent, indicating the products for which the agent is responsible.
- A certified BS/TSE certificate from the country of origin.
- A copy of the product's cover and leaflet printed on the company's letterhead, stamped by the company, and signed by an authorised person.
- A detailed composition certificate including the active and inactive ingredients and their quantities.
- A Summary of Product Characteristics (SPC).

The following circumstances constitute a variation to the MA that requires submitting a new MA application and results in the invalidation of the existing MA.

- A substantial change in the composition, formulation, dosage form, or strength of the medical product.
- A change in the product's classification or route of administration.
- Substantial changes in the manufacturing or production process that may affect the product's quality, safety, or efficacy.
- Substantial changes in the design of a medical device.
- Voluntary withdrawal of the medical product from the market with the intention of reintroducing it with significant changes.
- Pharmacovigilance findings requiring withdrawal, re-evaluation, or substantial modifications to the product.

The following constitute minor changes to the medical product. In such cases, the existing MA remains valid and a new application is not required. Instead, the MAH must submit an application to amend the MA.

- Minor changes in the product's composition.
- Introduction of new uses for the product.
- Changes in the appearance or leaflet of the product.
- Changes in the manufacturing location or the MAH's address.
- Minor changes in the manufacturing method.

The MA may be transferred from one MAH to another with the approval of the EDE. The process, terms, and conditions governing such transfers will be set out in the forthcoming Implementing Regulations of the Pharma Law.

3.5 Access to Pharmaceuticals and Medical Devices Without Marketing Authorisations

The Pharma Law introduces several exemptions to the requirement for a Marketing Authorisation.

Physicians may prescribe medical products without an MA under a compassionate use exception. The specific details, terms, and conditions governing compassionate use programmes will be set out in the forthcoming Implementing Regulations of the Pharma Law.

Medical products may also be issued an Emergency Use Authorisation. To obtain such authorisation, there must be evidence of the product's efficacy and benefits, supported by data from clinical research or trials. Additionally, there must be no adequate alternative treatment available, and a monitoring plan must be in place once the product is prescribed.

The following products may be granted a conditional MA, which is subject to less onerous application requirements and is valid for only one year.

- Orphan pharmaceutical or biological products for the treatment of rare diseases (provided the product has already been granted temporary approval in a reference jurisdiction).
- Medical products intended for the treatment of life-threatening or serious diseases.
- Medical products not currently available in the state for which no alternative exists.

3.6 Ongoing Obligations Imposed by Marketing Authorisations

The MAH must implement a comprehensive quality assurance system, a product traceability system, as well as a pharmacovigilance and post-marketing surveillance system.

The MAH must appoint one or more qualified persons based in the UAE. A qualified person is an individual who holds a valid licence to practice pharmacy or medicine within the UAE.

The MAH must appoint a minimum of two pharmaceutical establishments to act as importers of the medical product, as well as at least one pharmaceutical establishment to distribute the product. If the medical product is manufactured within the UAE, the MAH must additionally appoint at least one pharmaceutical establishment to store the product.

The MAH must monitor the movement of the medical product throughout the distribution channels.

The MAH must provide the necessary resources and systems required to meet all obligations associated with obtaining an MA.

The MAH must monitor the performance of the medical product and receive reports from healthcare establishments regarding its effectiveness, safety, and quality.

The MAH must comply with all guidelines and standards issued by the EDE relating to pharmacovigilance.

The MAH must follow up on all product recall procedures.

The MAH must also follow up on matters concerning the protection of patents and manufacturing rights for the product.

Under the UAE's Guidelines in Good Vigilance Practice (GVP Guidelines), no distinction is made between pharmaceuticals and medical devices; the guidelines apply similarly to both, where relevant.

Under the GVP Guidelines, the MAH must.

- Establish and maintain a system for the collection and recording of all reports of suspected adverse reactions, whether reported spontaneously by healthcare professionals or consumers, or observed in the context of a post-authorisation study.
- Put in place mechanisms that enable the traceability and follow-up of adverse reaction reports while complying with applicable data protection legislation. Pharmacovigilance data and documents relating to individual authorised medicinal products must be retained for as long as the product remains authorised, and for at least ten years after the MA has expired.

The EDE may issue a Medical Devices Field Safety Alert for certain medical devices. When this occurs, the manufacturer must provide users with a Field Safety Notice containing details of the Field Safety Correction Action.

Under Abu Dhabi's Standard on Medical Device Reporting, the MAH must report any deaths, serious injuries, malfunctions, and any public health risks requiring corrective action related to the medical device. The MAH must also report any non-urgent

safety matters, such as use errors, quality issues, or therapeutic failures.

3.7 Third-Party Access to Pending Applications for Marketing Authorisations

Pending applications are not made public.

MOHAP maintains a Registered Medical Products Directory, which contains information on approved medical products (not all fields apply to every product). The directory includes:

- trade name, classification, price, pack size, form, and strength (if applicable);
- supplier name and address;
- ingredients (if applicable);
- relevant body system;
- manufacturer and country of origin;
- dispensing mode; and
- first registration date.

Information relating to the approved MA for the relevant product is governed by the PDPL and the UAE Health Information Law, as applicable.

4. Regulatory Reliance and Fast-Track Registration Routes

4.1 Fast-Track Registration Routes

There is a Fast-Track Marketing Authorisation route for medical products that are innovative and of therapeutic significance.

The terms, controls, and requirement for the Fast-Track Marketing Authorisation are to be expanded upon in the forthcoming Executive Regulations of the Pharma Law.

4.2 Regulatory Reliance

The UAE has adopted the concept of regulatory reliance and takes into account marketing approvals granted in reference jurisdictions when evaluating a product's effectiveness, safety, and conformity with approved quality specification requirements.

The EDE may issue a conditional marketing approval for orphan medical or biological products intended for

the treatment of rare diseases, provided these products have received provisional approval from certain reference health authorities.

The EDE is preparing to update its list of authorised reference jurisdictions. Historically, however, it has accepted authorisations from the following regulatory authorities.

- The European Medicines Agency.
- The US Food and Drug Administration.
- The UK Medicines and Healthcare products Regulatory Agency.
- The Australian Therapeutic Goods Administration.
- The Swiss Agency for Therapeutic Products.
- Health Canada.
- The Japanese Ministry of Health – Pharmaceuticals and Medical Devices Agency.

5. Manufacturing of Pharmaceuticals and Medical Devices

5.1 Requirement for Authorisation for Manufacturing Plants

Manufacturing plants – referred to in the Law as Pharmaceutical Manufacturing Facilities – must be licensed by the EDE.

To obtain a licence from the EDE for a Pharmaceutical Manufacturing Facility, the applicant must:

- be the owner of the Pharmaceutical Manufacturing Facility;
- obtain a valid Good Manufacturing Practice (GMP) certificate from the EDE; and
- comply with the technical, health, and other requirements specified in the Implementing Regulation of the Pharma Law.

6. Distribution of Pharmaceuticals and Medical Devices

6.1 Wholesale of Pharmaceuticals and Medical Devices

Pharmaceutical establishments engaged in the wholesale of pharmaceuticals and medical devices must

obtain a licence from the EDE. An establishment conducting wholesale activities will primarily require a Medical Warehouse Licence.

The application for a Medical Warehouse Licence – to store and possess medical products – is submitted through the EDE online portal.

To obtain a Medical Warehouse Licence, the establishment must meet the following requirements.

- Obtain a valid Good Storage and Distribution Practice (GSDP) Certificate from the EDE.
- Appoint a licensed pharmacist for the technical management of the medical warehouse. If the medical warehouse's activities are limited only to medical devices, then the medical warehouse may appoint a medical devices engineer or specialist instead of a pharmacist.
- Secure approval from the UAE Ministry of Economy and Tourism regarding foreign ownership share percentages if the medical warehouse is located outside a free zone.

In addition to the Medical Warehouse Licence, the pharmaceutical establishment must also obtain an EDE licence for any of the following activities:

- import;
- export;
- re-export; and/or
- distribution.

The Executive Regulations of the Pharma Law will also specify any additional activities requiring a licence. These Regulations have not yet been released.

A Biobank, Pharmaceutical Laboratory, Non-Clinical or Clinical Research Entity, Bioequivalence Center, Medical Products Factory, or a contracted Medical Products Manufacturing Company may also obtain activity permits from the EDE.

6.2 Different Classifications Applicable to Pharmaceuticals

Pharmaceuticals may be classified as follows.

- Over-the-counter medicines – non-prescription pharmaceutical products available for purchase without the need for a prescription.
- Pharmacist-only medicines – pharmaceutical products that must be dispensed by a pharmacist, though a prescription is not required.
- Prescription-only medicines – pharmaceutical products that must be dispensed by a pharmacist and require a valid prescription issued by a licensed practitioner.
- Semi-controlled drugs – non-narcotic pharmaceutical products that may provide medical benefits but carry risks of habituation or addiction, particularly with long-term use, high doses, or when combined with other substances.
- Controlled drugs – pharmaceutical products that require special control procedures. This includes toxic substances, certain plants, prohibited veterinary substances, narcotic and psychotropic substances, and other hazardous medical products.
- Narcotics – products as defined and listed under Federal Decree-Law No 30 of 2021 on Combating Narcotics and Psychotropic Substances.
- Non-registered drugs – when no registered pharmaceutical product is available, a health facility may apply to the Ministry of Health and Prevention for authorisation to procure a non-registered pharmaceutical product.

The UAE is a signatory to the United Nations Office on Drugs and Crime's International Drug Control Conventions. These international commitments are reflected in national legislation governing drug classification and the control of narcotic and psychotropic substances.

7. Import and Export of Pharmaceuticals and Medical Devices

7.1 Governing Law and Relevant Enforcement Bodies

The Pharma Law governs the importation and exportation of pharmaceuticals and medical devices.

The EDE is responsible for issuing the permits and licences required for such import and export activities.

The UAE Federal Customs Authority enforces the import regulations at the point of entry, after which enforcement is carried out by the EDE. The DHA and the DOH may also participate in enforcing the import regulations within their respective Emirates, working in co-ordination with the EDE.

7.2 Importer of Record of Pharmaceuticals and Medical Devices

The Pharma Law defines an "importer" as a legal entity licensed by the EDE to import medical products into the UAE.

To obtain an EDE import licence, the legal entity must meet the following requirements.

- Obtain the product's Marketing Authorisation from the EDE.
- Ensure that the local agent listed in the product's MA is the party responsible for carrying out the importation.
- Secure electronic approval for the shipment from the UAE Federal Customs Authority.
- Include a commercial invoice for the product with each initial import permit request.
- Undergo an inspection at the customs port conducted by EDE inspectors.
- Complete an inspection for the purpose of releasing the shipment for distribution in the local market.

Additionally, the holder of the MA must appoint at least two pharmaceutical establishments to import the medical products into the UAE, and must appoint at least one pharmaceutical establishment to distribute the products.

7.3 Prior Authorisations for the Import of Pharmaceuticals and Medical Devices

See 7.1 Governing Law and Relevant Enforcement Bodies and 7.2 Importer of Record of Pharmaceuticals and Medical Devices.

There are no exemptions from the importation authorisations, including for over-the-counter pharmaceuticals and medical devices.

To import a pharmaceutical product or medical device for personal use, an individual must apply for a sepa-

rate Permit to Import Medicines for Personal Use. The individual must provide a valid prescription and a valid medical report detailing their clinical history.

A standard import permit is valid for two months.

7.4 Non-Tariff Regulations and Restrictions Imposed Upon Imports

Non-tariff regulations and restrictions on importation are applied based on the Harmonised System (HS) Code of the product. The UAE is currently undertaking a phased implementation of the Gulf Cooperation Council (GCC) Integrated Customs Tariff (“Integrated Tariff”). Under this model, the previous six-digit HS codes will be replaced with a standardised 12-digit code used consistently across the GCC. The Integrated Tariff framework remains based on the HS. To support correct product classification, Dubai Customs has developed an AI-powered online platform called AI Munasiq.

The legal framework governing the use of both the HS codes and the Integrated Tariff Model is set out in Federal Decree-Law No 15 of 2022 on the Ratification of the Common Customs Law of the GCC (“Common Customs Law”). In addition, Federal Decree-Law No 14 of 2021 on the Establishment of the Federal Authority for Identity, Citizenship, Customs and Ports Security regulates the UAE Federal Customs Authority.

Dubai Customs Notice No 10 of 2025 and Notice No 2 of 2026 outline the phased approach for implementing the Integrated Tariff and confirm that the previous eight-digit code may continue to be used until further notice.

7.5 Trade Blocs and Free Trade Agreements

The UAE is a member of the GCC, which operates under a unified customs law implemented in the UAE through the Common Customs Law. Although a unified customs agreement exists, entities must still obtain an import permit when importing products from a GCC member state into the UAE, even if those products may be exempt from duties or tariffs.

The UAE is also a party to more than 25 Free Trade Agreements (FTAs), including the UAE–Singapore

FTA, the UAE–EFTA FTA, and the UAE–Türkiye FTA, all of which include provisions relating to customs and trade facilitation.

8. Pharmaceutical and Medical Device Pricing and Reimbursement

8.1 Price Control for Pharmaceuticals and Medical Devices

Prices of pharmaceuticals and medical devices are controlled by the EDE. Under the Pharma Law, the Pharmaceutical Policy Committee is the dedicated body responsible for proposing policies related to the circulation, pricing, and monitoring of pharmaceuticals and medical devices.

According to Cabinet Decision No 90 of 2021 on the Implementing Regulation of Federal Law No 8 of 2019, prices set by the EDE or MOHAP may not be discounted or altered, except by the EDE or MOHAP themselves. Once the Implementing Regulations for the Pharma Law are issued, Cabinet Decision No 90 of 2021 will be abrogated.

Pharmaceutical prices are regulated under Ministerial Decision No 140 of 2013 on the Unification of the Price of Import of Drugs from the Factory at the Country of Origin on a CIF basis, priced in USD (the “Pricing Law”).

Under the Pricing Law:

- the price of imported pharmaceuticals is tied to the country of origin and is not determined by the distributor or agent;
- a standardised reference formula is used to set prices – the Pharmacy Price equals the import price plus 15% of the import price, calculated in Emirati dirham (AED); and
- pharmaceuticals sold to the public in pharmacies are then priced according to three categories, depending on the Pharmacy Price.

Pricing decisions are published through Ministerial Decisions and may vary by Emirate. For example, the DHA may set different prices from the DOH, although prices may also be established at the federal level.

8.2 Price Levels of Pharmaceuticals or Medical Devices

The EDE may take into account the prices for the same products in other countries if they are imported into the UAE.

See 8.1 Price Control for Pharmaceuticals and Medical Devices. The formula for determining the price of a pharmaceutical and medical device is:

Pharmacy Price = Import Price + 15% of the Import Price (in AED). The Import Price is calculated first as USD, then converted into AED.

The Sale Price of pharmaceuticals and medical devices depends on the Import Price.

- If the Import Price is less than AED250, then the Sale Price is calculated as = Pharmacy Price + 28% of the Import Price (in AED).
- If the Import Price is between AED250 and AED500, then the Sale Price is calculated as = Pharmacy Price + 24% of the Import Price (in AED).
- If the Import Price is greater than AED500, then the Sale Price is calculated as = Pharmacy Price + 20% of the Import Price (in AED).

Note that, notwithstanding the above, the EDE retains discretion regarding the pricing of medical products.

8.3 Reimbursement From Public Funds

In the UAE, reimbursement for medical products is governed primarily at the emirate level. Reimbursement occurs through government-funded programmes rather than a single national health service. Cabinet Resolution No 87 of 2023, which establishes the Supreme National Committee for Unified Procurement (“Procurement Resolution”), sets the framework for the federal Unified Procurement Program (UPP). The UPP aligns procurement processes for government programmes within the health sector, although reimbursement mechanisms may change once the Implementing Regulations are released.

Dubai

Pharmaceuticals used for insured patients (including those in public hospitals) are reimbursed indirectly

through the Diagnosis Related Group (DRG) payment system.

Under this model, inpatient pharmaceuticals are bundled into DRG tariffs. These tariffs cover hospital stays, clinical procedures, ancillary services, and associated medications based on a patient’s diagnosis. As a result, routine inpatient medications are funded through public or mandatory insurance payments rather than reimbursed on an itemised basis.

Medications prescribed in outpatient settings are reimbursed based on the patient’s health insurance coverage policies or DHA-approved formularies, with eligibility dependent on clinical necessity or DHA guidelines.

Similar reimbursement principles apply to medical devices. Routine devices used during inpatient care fall under DRG bundled payments, requiring hospitals to manage these costs within fixed tariffs. This incentivises efficient and clinically appropriate use.

High-cost or specialised devices – such as implants and surgical prostheses – may be reimbursed through additional payment parameters or DRG outlier adjustments. These usually require prior authorisation and clinical justification.

In public hospitals, essential medical devices may also be provided free of charge to patients, funded by federal or emirate-level health budgets, provided they meet clinical effectiveness and cost-effectiveness criteria.

Reimbursement from public funds requires compliance with DHA coding standards, DRG submission rules, and ISAHD claims adjudication requirements, as set out in relevant guidance circulars.

Abu Dhabi

The Department of Health has implemented the UPP for government programmes. Reimbursement of health services, including medical products, is governed by the DOH’s Claims and Adjudication Rules and its Circulars. These establish how medical products are procured, funded, and dispensed.

For UPP-listed pharmaceuticals, reimbursement is generally limited to the permitted markup on the public price. Reimbursement is only allowed if the medical product falls under government-funded insurance programmes (including Thiqa, basic health insurance, and Abu Dhabi-funded mandates).

Medical products not included in the UPP but covered under approved government programmes – ie, those provided free of charge or subsidised – are reimbursed at the public drug price.

Under DOH rules, medical devices are incorporated into bundled payments for inpatient and ambulatory services, particularly under the IR-DRG methodology.

8.4 Cost-Benefit Analyses

There is currently no federal Health Technology Assessment (HTA) framework in the UAE. As of 2025, Abu Dhabi is the only emirate with a formal HTA system in place, which focuses on new and innovative technologies.

Notwithstanding the above, Cabinet Resolution No 87 of 2023, which established the Supreme National Committee for Unified Procurement (“Procurement Resolution”), addresses – at least in part – principles relevant to cost-benefit considerations.

One of the overarching principles guiding the federal Committee for Unified Procurement (“Committee”) is “achieving financial savings” within the unified procurement system.

This principle is supported by the Committee’s authority to identify procurement opportunities, assess the medical products market, and monitor the negotiations between suppliers and manufacturers.

The DOH issued the HTA Guidelines, which outline how economic evaluations are to be carried out under the HTA process.

Prior to the recommendation of new or innovative health technologies, economic evaluations are conducted in order to determine if they should be recommended or not. This involves the following.

- A cost-effectiveness analysis, which considers costs and health outcomes against alternative health technologies.
- Budget-impact analysis – assessing both short-term and long-term budgetary implications.
- Therapeutic added-value – evaluating the clinical benefits of the new technology relative to existing options.

A new or innovative product cannot be considered without an HTA submission addressing all three factors above.

HTA findings are also taken into account when determining the pricing of pharmaceuticals, medical devices, and medical services. However, pricing decisions are not based solely on a cost-benefit assessment; rather, all three evaluation factors are considered.

For reimbursement purposes, Abu Dhabi government insurance programmes will reimburse a pharmaceutical product or medical device after the manufacturer or distributor submits an HTA dossier containing the relevant clinical and economic evidence. These HTA dossier submissions are assessed according to the product’s clinical effectiveness, cost-effectiveness, budget impact, and therapeutic added value.

8.5 Regulation of Prescriptions and Dispensing by Pharmacies

Prescriptions and dispensations are regulated at the federal level under the Pharma Law, and at the emirate level by the DHA and DOH.

In Dubai, according to the DHA’s Pharmacy Guidelines, pharmacists may only dispense the medical product specifically prescribed. They are prohibited from directing customers toward any other medical products that are not included in the prescription.

Within Dubai Healthcare City Freezone, additional regulations apply on top of federal and emirate-level rules. A pharmacist may not dispense a generic equivalent if the prescription includes a note prohibiting substitutions. A generic may also not be dispensed if its price is the same as or higher than the prescribed brand. If the prescription does not prohibit substitutions, the pharmacist may dispense a generic equivalent.

lent, provided the patient is informed that a cheaper alternative exists and is given the choice between the branded and generic drug.

Under the DRG regime in Dubai, prescriptions fall within a fixed reimbursement amount. This indirectly incentivises cost-effective prescribing and treatment choices.

In Abu Dhabi, the DOH's Standard for the Prescribing and Dispensing of Generic Medicines ("Prescription Standard") requires pharmacists not to dispense a branded medical product when the prescription specifies a generic product. However, if a specific branded product is prescribed, the pharmacist may not dispense a generic substitute when a "Do Not Substitute (DNS)" note is included. The Prescription Standard also sets out several circumstances in which pharmacists may not offer generic alternatives for specific or branded prescriptions.

Under Abu Dhabi's implementation of the UPP framework, providers are reimbursed based on fixed markups rather than the full product price. This discourages the prescribing of higher-priced medical products when a cheaper alternative is available.

Trends and Developments

Contributed by:

Winsome Cheung and Haykel Hajjaji
Covington & Burling LLP

Covington & Burling LLP offers one of the world's largest and most comprehensive life sciences-focused practices. Its clients – spanning every sector and ranging from emerging biotech ventures to global pharmaceutical companies and major trade associations – trust the firm with their most complex business challenges. The firm has clients across the entire product life cycle, going well beyond traditional legal services to enable efficient R&D, successful launch and commercialisation, and long-term value maximisation. Covington supports numerous leading life sciences companies on strategic transactions,

M&A, financings, and emerging issues including digital health, post-Brexit regulatory divergence, privacy, innovation incentives, reimbursement, and evolving medical device and diagnostic regulations. It also guides clients through rapidly shifting political and policy landscapes, including drug-pricing initiatives and implications for compliance, trade, antitrust, and litigation. The team includes more than a hundred dedicated life sciences lawyers, many of whom previously held senior positions at regulatory agencies, major manufacturers, or industry associations.

Authors



Winsome Cheung is a partner at Covington & Burling LLP who represents global pharmaceutical and biotechnology companies on strategic partnering and collaboration arrangements. A former scientist with

a PhD in medicine, she draws on deep scientific and industry insight to advise clients across the life sciences value chain. She leads major cross-border licensing and collaboration transactions, including high-value alliances, option agreements, and asset acquisitions. Winsome also advises on ecosystem-wide initiatives, including serving as a chief legal adviser to a global antiviral consortium, and long-term strategic partnerships in genomics. She regularly counsels investors and biotechnology companies on IP licensing, manufacturing, and commercial agreements.



Haykel Hajjaji is a partner at Covington & Burling LLP who advises global corporations, sovereign investors, and financial institutions on complex cross-border transactions, regulatory strategy, and market entry

across the Middle East. His practice spans corporate, M&A, and commercial advisory matters, with a focus on strategic expansion into the Gulf. Haykel has deep expertise at the intersection of innovation, regulation, and geopolitics, particularly across AI, data centres, life sciences, defence, supply chain, and infrastructure. With over two decades of experience, he counsels clients on market entry, transaction structuring, foreign investment regimes, and legal risk in sensitive environments.

Covington & Burling LLP

Office No. 703, Level 7
Gate Precinct Building 3
Dubai International Financial Centre
P.O. Box: 507082
Dubai
UAE

Tel: +971 4 247 2100
Email: CFoster@cov.com
Web: www.cov.com/en/

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Regulatory Modernisation and Market Dynamics Shaping the UAE's Life Sciences Sector

Introduction

The United Arab Emirates is undergoing a sustained transformation of its life sciences sector. Over recent years, and with particular acceleration since 2023, the federal government has implemented extensive regulatory reforms, expanded clinical research capacity, and introduced industrial and innovation policies aimed at positioning the UAE as a regional hub for pharmaceuticals, biotechnology and advanced healthcare solutions. These developments form part of a broader national agenda focused on economic diversification, knowledge-based industries and long-term healthcare resilience.

Life sciences has emerged as a priority sector within this agenda. Policy initiatives increasingly emphasise local manufacturing, research and development, and the adoption of advanced technologies across the healthcare ecosystem. As a result, the UAE market is now characterised by heightened regulatory sophistication, clearer institutional structures, and closer alignment with international regulatory standards.

At the same time, the pace and breadth of reform require careful monitoring. New federal legislation continues to be supplemented by executive regulations and regulatory guidance, and market participants must navigate the interaction between federal and Emirate-level rules, as well as the interfaces between different health authorities. This article examines the principal trends shaping the UAE life sciences sector and highlights their practical implications for companies operating in, or considering entry into, the market.

Market and deal trends

In parallel with regulatory reform, the UAE has experienced increased activity in healthcare and life sciences transactions across public markets, strategic M&A, venture investment, and licensing. The market continues to be shaped by government-affiliated players, healthcare platforms, and a growing pipeline of digital health and data-driven healthcare companies.

UAE public markets are becoming more significant as exit and funding routes for major healthcare platforms.

Notably, PureHealth listed on the Abu Dhabi Securities Exchange (ADX) in December 2023.

The UAE remains one of the Middle East's leading M&A markets. Healthcare M&A is driven by platform consolidation, portfolio optimisation, and the acquisition of technology-enabled service capabilities. Venture capital plays an increasingly important role, especially in healthtech and data-enabled healthcare models.

Licensing transactions are also becoming more prominent. Most licensing involving UAE-based companies takes the form of inbound licensing of products, technologies, or know-how, reflecting a national focus on building domestic capabilities and accelerating access to innovative healthcare solutions. These licences are often granted for the entire GCC/MENA region, consistent with the UAE's role as a regional commercial hub. Recent developments also suggest diversification beyond traditional pharmaceutical licensing toward diagnostics, digital health, data analytics, and platform-based healthcare solutions, frequently implemented through large, government-affiliated healthcare platforms.

Regulatory consolidation and modernisation

A defining recent development is the consolidation and modernisation of the regulatory framework governing medical products and pharmaceutical activities. Federal Decree-Law No 38 of 2024, effective January 2025, represents a comprehensive overhaul of the previous regime and significantly expands the scope of regulated products and entities.

The law explicitly covers pharmaceuticals, biopharmaceuticals, medical devices, food supplements, cosmetics, advanced therapy products, clinical research entities, and biobanks. This broader scope reflects the convergence of healthcare technologies and the need for a unified framework capable of regulating both traditional products and emerging therapies.

The legislation also formalises the role of the Emirates Drug Establishment as the central federal authority responsible for marketing authorisations, pharmacovigilance, pricing oversight, and national product tracking systems. This restructuring aims to reduce

historic fragmentation between federal and Emirate-level regulators and to promote a more predictable, transparent, and globally aligned regulatory environment.

For companies, the expanded regulatory landscape means a greater range of activities now fall under formal licensing and supervision. Organisations involved in research, manufacturing, marketing, or distribution must adopt a more holistic approach to assessing their regulatory footprint, especially where activities span multiple product categories or involve cross-border operations.

Institutional co-ordination and regulatory practice

Although regulatory authority is increasingly centralised at the federal level, Emirate-level health authorities continue to play a critical role in licensing healthcare facilities, practitioners, and research sites. Companies must therefore navigate a layered regulatory environment, particularly when conducting clinical trials or operating healthcare facilities in specific Emirates.

Co-ordination between federal and local authorities has improved, but differences in administrative processes and timelines may persist. Early engagement with relevant regulators and a clear understanding of jurisdictional competencies remain essential to managing approval pathways and mitigating compliance risks.

As the new federal framework is implemented, regulatory practice continues to evolve. Authorities are developing internal procedures, digital platforms, and guidance materials. Companies should anticipate a period of adjustment as expectations become clearer through practice rather than formal rule-making alone.

Market access and approval pathways

The updated regulatory framework introduces new market access pathways designed to support innovation and timely patient access. These include conditional marketing authorisations for orphan and rare disease treatments, emergency use authorisations, and fast-track procedures for innovative medical products addressing significant therapeutic needs.

These mechanisms aim to shorten approval timelines while maintaining safety and efficacy standards. For innovative companies, the availability of differentiated pathways may influence clinical development strategies, launch sequencing, and regional investment decisions.

However, the operation of these pathways is closely tied to regulatory discretion and detailed implementing guidance. Companies aiming to use accelerated or conditional approvals must be prepared for intensive engagement with regulators and must meet post-authorisation obligations.

Pricing and reimbursement dynamics

Pricing and reimbursement remain central to market access strategy. Pharmaceutical pricing is subject to regulatory oversight, with authorities seeking to balance affordability, supply security, and incentives for innovation.

There are signs of increased openness to value-based considerations, particularly for innovative therapies targeting serious or rare conditions. Nonetheless, pricing negotiations can be complex, with outcomes influenced by product category, therapeutic area, and anticipated patient population.

Reimbursement occurs through government-funded programmes administered largely at the Emirate level. In 2023, the UAE established a Supreme National Committee for Unified Procurement to introduce a federal procurement programme aimed at achieving financial efficiencies; however, implementing regulations are still pending, and mechanisms may evolve.

For companies entering the UAE, pricing strategy should be integrated early into regulatory planning, as misalignment between approval and pricing processes can impact launch timelines and commercial viability.

Clinical research and trials environment

Clinical research has emerged as a strategic pillar of the UAE's life sciences ecosystem. Since 2023, federal reforms have created a more coherent national framework for clinical trials, including licensing requirements for sponsors, investigators, and CROs,

as well as enhanced ethical oversight and reporting obligations.

The framework aims to balance patient protection with international credibility, positioning the UAE as a destination for multinational and multi-centre clinical studies. Centralised oversight and clearer procedures are expected to improve alignment with global Good Clinical Practice standards and reduce approval uncertainty.

Abu Dhabi and Dubai have become key centres for clinical research due to advanced healthcare infrastructure, specialised research institutions, and growing public-private collaboration. For sponsors, the UAE offers access to diverse patient populations and increasingly efficient regulatory processes, although early regulatory engagement remains critical.

Research infrastructure and partnerships

Investment in research infrastructure has expanded in parallel with regulatory reform. Public sector institutions, academic centres, and healthcare groups are playing increasingly active roles in clinical research, often partnering with international sponsors and CROs.

Public-private partnerships are particularly influential. Government-backed healthcare groups and research entities frequently participate in clinical studies, offering access to facilities, patient populations, and local expertise. For international sponsors, such partnerships can facilitate market entry and operational efficiency, although they require careful structuring and governance.

Genomics, precision medicine and biobanking

One of the most distinctive developments in the UAE life sciences landscape is the rapid expansion of genomics-driven healthcare. The Emirati Genome Programme is a flagship initiative aimed at supporting precision medicine by mapping the genetic profile of the Emirati population and integrating genomic data into clinical practice and public health planning.

A dedicated federal legal framework governs the collection, use, and protection of genomic data, with strong emphasis on informed consent, ethical use,

data security, and restrictions on non-therapeutic genetic interventions.

For life sciences companies, growing genomics infrastructure creates opportunities in personalised medicine, diagnostics, population health analytics, and genomics-enabled drug discovery. However, it also imposes heightened compliance obligations, particularly around data governance, secondary use of samples, cross-border collaboration, and long-term data storage.

Biobanking and data use

Biobanks are now explicitly regulated and subject to licensing and oversight. This reflects the growing importance of biological samples and associated data in research and innovation.

Companies engaging with biobanks must ensure that contracts, consent frameworks, and data-use practices comply with regulatory requirements – particularly for collaborative research involving international partners or cross-border data transfers.

Pharmaceutical manufacturing and industrial strategy

The UAE has strengthened its focus on domestic pharmaceutical and medical product manufacturing as part of its broader industrial strategy. Life sciences manufacturing is a priority sector under Operation 300bn, the national programme aimed at increasing industrial contributions to GDP and enhancing supply chain resilience.

Companies can access a range of financial and structural incentives, including preferential financing, support for advanced technology adoption, and export-oriented production. These incentives are supported by regulatory reforms designed to streamline licensing, inspection, and oversight.

Dedicated life sciences zones and industrial clusters in Abu Dhabi and Dubai continue to attract international pharmaceutical and biotechnology companies establishing regional manufacturing, logistics, and distribution bases.

Supply chain and localisation considerations

Supply chain resilience has become a major policy priority, particularly in response to recent global disruptions. Authorities are encouraging local production of essential medicines and medical products, as well as diversification of sourcing strategies.

For companies, this presents both opportunities and expectations. Local manufacturing and technology transfer may provide advantages in regulatory and procurement contexts but require careful assessment of feasibility, scale, and cost.

Commercial structures and market entry

The evolution of the life sciences regulatory environment has coincided with broader reforms to the UAE's commercial and corporate framework. Companies entering the market must consider corporate structuring, distribution models, commercial agency rules, and competition law.

Although reforms have increased flexibility in ownership and commercial structures, regulated activities still require alignment between corporate form and regulatory approvals. The identity of the licensed entity, its operational location, and the scope of authorised activities must all be consistent across corporate and regulatory documents.

Distribution arrangements remain a key consideration. While reforms have reduced some of the rigidity of historic commercial agency rules, legacy arrangements and sector-specific norms continue to shape market entry strategies.

Digital health and technology integration

Digital health continues to grow across the UAE healthcare system. Telemedicine and remote care services are supported by established federal and Emirate-level regulatory frameworks addressing licensing, standards of care, data security, and professional liability.

These frameworks have enabled continued adoption of digital healthcare services beyond the pandemic, with telehealth increasingly integrated into routine care. Providers must meet the same clinical and ethical standards as in-person care, and certain services

remain restricted where physical examination is necessary.

In parallel, the UAE's national strategy for artificial intelligence is shaping the development and deployment of AI-enabled tools in diagnostics, research, and healthcare delivery. Regulatory expectations centre on transparency, accountability, and human oversight, which will influence future approvals of AI-driven medical technologies.

Data protection and health data governance

Data governance is a critical consideration for life sciences operators in the UAE. The Federal Personal Data Protection Law applies to the processing of personal and sensitive health data, including clinical trial and genetic data.

Although executive regulations continue to develop, organisations are expected to implement governance frameworks aligned with international data protection standards. Particular focus is required for cross-border data transfers, data localisation, and breach notification obligations.

Health data is also governed by federal and Emirate-level frameworks, including Federal Law No 2 of 2019, and regulations issued by the Abu Dhabi Department of Health and the Dubai Health Authority. Health data must remain confidential and may not be stored, transferred, or processed outside the UAE. The transfer of health data is also regulated by Ministerial Decision No 51 of 2021, which sets out restrictions and exemptions relating to the transfer of health data. Approval from the Emirate-level regulators is required for the transfer of health data outside of the UAE in certain cases.

For companies operating across multiple jurisdictions, aligning UAE-specific requirements with global data governance programmes remains challenging – particularly where research or digital health operations rely on centralised data platforms.

Outlook

The UAE life sciences sector is characterised by rapid regulatory evolution, significant public investment and strategic direction. While the regulatory environment is

UAE TRENDS AND DEVELOPMENTS

Contributed by: Winsome Cheung and Haykel Hajjaji, **Covington & Burling LLP**

becoming more structured and predictable, ongoing legislative and regulatory developments require continued attention, particularly as implementing regulations and regulatory guidance are issued.

For companies aligned with national health, innovation and industrial priorities, the UAE offers a dynamic and increasingly sophisticated market. Over the medium term, sustained investment in regulation, infrastructure, research and talent development is likely to further strengthen the country's position as a leading life sciences hub in the region.

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