TRADE AND DISTRIBUTION OF THERAPEUTIC PRODUCTS (PHARMACEUTICALS/BIOLOGICS AND MEDICAL DEVICES)

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REGULATORY FRAMEWORK AND COMPETENT AUTHORITIES

1. What are the principal statutes, regulations, and competent authorities that govern the import, wholesale distribution, retail sale, and export of therapeutic products (ie, for pharmaceuticals/biologics and medical devices, noting any separate or overlapping regimes)? In the case of a federal state, what is the division of powers between the federal government and the states?

Therapeutic products are regulated in the United Arab Emirates (UAE) by the Emirates Drug Establishment (EDE), which is the federal regulatory authority responsible for regulating and controlling medical and pharmaceutical products and devices. The Ministry of Health and Prevention (MOHAP), which previously exercised these regulatory functions as the national regulator before the establishment of the EDE, retains a limited transitional and policy-oriented role pending full implementation of the new regulatory framework set out below. The import and export of therapeutic products are subject to permit requirements administered by the EDE, and an EDE-issued permit is required to import or export therapeutic products lawfully for wholesale distribution.

Therapeutic products are governed by a single principal statute, Federal Decree-Law No. (38) of 2024 Governing Medical Products, Pharmacists and Pharmaceutical Establishments (MPL), which came into force on 2 January 2025, replacing Federal Law No. (8) of 2019 Concerning Medical Products, Pharmacists and Pharmaceutical Establishments (Previous Medical Products Law). Each Federal Decree-Law is typically followed by an executive regulation which sets out the legislative position in the Federal Decree-Law. The corresponding executive regulations to the MPL have yet to be issued (MPL Executive Regulations). In the interim, the executive regulations applying to the Previous Medical Products Law shall remain in force to the extent they do not contradict the provisions of the MPL, until the MPL Executive Regulations are issued.

The MPL employs a unified framework for therapeutic products under the umbrella term ‘medical products’. This specifically includes pharmaceutical products (including biologics, regulated as ‘biopharmaceutical products’) and medical equipment (devices) (‘medical devices’) (together, ‘medical products’). Under the MPL, medical products may not be imported, distributed, possessed, sold, displayed, re-marketed, used, or manufactured in the UAE without prior marketing authorisation from the EDE, subject to limited exemptions.

The EDE exercises comprehensive federal regulatory authority over the approval, registration, import, export, distribution, and sale of therapeutic products. However, the implementation of federal pharmaceutical regulation is decentralised to local Emirate healthcare authorities (the Local Healthcare Regulator). In practice, the most developed local regulatory frameworks operate

in the Emirates of Dubai and Abu Dhabi. The Dubai Health Authority (DHA) serves as the local health regulator for the Emirate of Dubai, excluding the healthcare-free zone Dubai Healthcare City; whereas the Abu Dhabi Department of Health (DOH) performs equivalent functions in the Emirate of Abu Dhabi.

Dubai Healthcare City operates its own healthcare regulatory regime for establishments operating within the free zone, although therapeutic products remain subject to the federal MPL framework and EDE oversight.

2. How are therapeutic products classified for regulatory purposes (eg, prescription-only, over-the-counter, hospital-use, risk classes for devices, etc.) and what legal consequences attach to each classification with respect to trade and distribution? In particular, is premarket review and approval required by a competent authority?

Pharmaceutical products

In the context of pharmaceutical products, the MPL establishes regulatory categories for Medical Products, based on access requirements and risk profiles: (1) medical products requiring prescription for dispensing; (2) medical products which do not require prescription; (3) controlled products and semi-controlled products; and (4) medical products for compassionate use.

The classification of the medical product affects the restrictions and limitations on trade and distribution, including points of sale, dispensing conditions, prescription requirements, record-keeping obligations and enhanced controls, particularly for narcotic and psychotropic substances.

Premarket review and approval are mandatory for all medical products. No medical product may be imported, distributed, possessed, sold, displayed, re-marketed, used, or manufactured unless it has first obtained marketing authorisation from the EDE.

The MPL establishes different types of marketing authorisation which apply primarily to pharmaceutical products (including biologics). These include: (1) Standard Marketing Authorisation (valid for five years and renewable); (2) Conditional Marketing Authorisation (for orphan products, life-threatening disease products, or unavailable products, valid for one year and renewable); (3) Emergency Use Authorisation (during health emergencies, valid for the emergency duration); and (4) Fast-track Authorisation (for innovative or therapeutically important products).

Any change to the classification or essential characteristics of a medical product requires a new or amended marketing authorisation.

Medical devices

The EDE applies a risk-based classification system broadly for medical devices, aligned with international frameworks (including the Global Harmonisation Task Force principles), categorising devices into Classes I, II, III, and IV (with increasing regulatory control as risk increases), and in vitro diagnostic devices into Classes A, B, C, and D.

Lower-risk medical devices are subject to streamlined registration procedures, while higher-risk medical devices require more extensive technical, safety, and performance documentation.

While risk classification may indirectly influence how devices are supplied and used in practice, distribution channels in the UAE are not solely determined by classification. Instead, they depend on a combination of factors, including the device's intended use, labelling (eg, professional use or over-the-counter), and applicable licensing requirements for distributors and points of sale.

Classification and registration are assessed by the EDE on a case-by-case basis. Although classification principles broadly align with international standards, there is limited explicit guidance linking specific risk classes to prescribed distribution channels.

LICENSING, AUTHORISATIONS, AND DISTRIBUTION CHANNELS

3. Which licences, authorisations, registrations, or other official permissions are required for businesses to engage in wholesale distribution of therapeutic products, and what key conditions (such as Good Distribution Practice, facility standards, personnel, insurance, or financial guarantees) attach to them?

Businesses engaging in wholesale distribution of therapeutic products in the UAE operate under a multi-tier licensing framework involving federal and Emirate-level approvals.

At the commercial level, businesses must obtain a commercial licence from the relevant economic development authority in the Emirate where they are seeking to operate and conduct business. In Dubai, this is issued by the Department of Economy and Tourism, in Abu Dhabi it is the Department of Economic Development. This commercial licence establishes the legal entity and permits it to operate within the Emirate, subject to obtaining regulatory approval.

Additionally, pharmaceutical establishments require a health facility licence from the relevant Local Healthcare Regulator in the Emirate where they are seeking to operate and conduct business. For example, in Dubai, this is handled by the DHA, while in Abu Dhabi, licensing is handled by the DOH. The Local Healthcare Regulators are required to notify the EDE of all licences issued and related information to ensure coordination between federal and local regulatory oversight.

At the federal level, wholesale distributors must also obtain the relevant medical warehouse authorisation under the EDE regulatory framework and demonstrate Good Distribution Practice (GDP) and Good Storage and Distribution Standards.

The technical management of a medical warehouse must be entrusted to a licensed pharmacist who is responsible for the medical warehouse and dedicated to it on a full-time basis. In practice, this requires the individual to be dedicated to the licensed facility and not to hold equivalent responsible person roles across multiple warehouses concurrently. The responsible person is accountable for compliance with the MPL and related EDE and Local Healthcare Regulator's regulations, and is expected to be available to exercise effective oversight of the facility. For medical warehouses dealing exclusively with medical devices, the responsible person may alternatively be a licensed Medical Device Engineer or another appropriately qualified and licensed specialist in a health profession, subject to acceptance by the EDE and/or the relevant local healthcare regulator. In practice, eligibility will depend on the individual's qualifications, professional licence, and demonstrated relevant expertise to the handling and oversight of medical devices. The MPL and related guidance do not prescribe an exhaustive list of qualifying health professions for this purpose, and approvals are typically assessed on a case-by-case basis.

A medical warehouse engaged in import or export activities must obtain specific federal authorisation for such activities. Each import, export, or re-export shipment requires a permit or approval issued in accordance with the EDE import/export framework.

Medical warehouses must maintain comprehensive general records covering all operations, as well as special records for controlled materials and products, and semi-controlled products. The EDE-set price must be attached to the external packaging of all medical products, and the importer or manufacturer name must be clearly identified.

Medical warehouses are banned from engaging in activities not covered by their licence, selling to unlicensed persons or establishments, purchasing from unlicensed entities, or selling at prices above or below EDE-set price levels.

The MPL does not explicitly stipulate insurance or financial guarantee requirements for medical warehouse licensing. Such requirements, if any, would be specified in the MPL Executive Regulations or other implementing decisions.

As a matter of market practice, international manufacturers commonly appoint UAE-licensed local distributors who already hold the necessary regulatory approvals, thereby allocating day-to-day local regulatory and operational responsibilities to the local entity. However, the appointment of a local distributor does not, in itself, extinguish the international manufacturer's own regulatory obligations to the EDE, including in relation to product registration, safety monitoring and product quality. While the parties may allocate responsibilities contractually as between themselves, such arrangements operate as between the parties only and do not displace or limit obligations owed to the EDE.

4. Are there distinct licensing or notification requirements for businesses that provide therapeutic products directly to consumers (including community pharmacies, internet pharmacies, or other retailers), and what key conditions attach to them?

Medical warehouse licences authorise storage and distribution to other licensed entities but do not permit direct retail supply to consumers.

Entities that supply therapeutic products directly to individual consumers are subject to a separate licensing regime for pharmacies and must comply with specific regulatory conditions relating to premises, dispensing practices, record-keeping, and supervision.

A licensed pharmacist must be appointed and dedicated to the pharmacy full-time.

Retail supply of pharmaceutical products (including biologics) to consumers is generally restricted to licensed pharmacies, and sale through other retail channels is not permitted. The retail supply of Medical Devices is also regulated and, depending on the risk classification and intended use, may be limited to licensed pharmacies or authorised healthcare facilities, with higher-risk Medical Devices restricted to professional or institutional channels.

The UAE regulatory framework also permits online and electronic pharmacy services, subject to prior approval by the relevant Local Healthcare Regulator and compliance with specific conditions relating to prescription verification, pharmacist supervision, delivery controls and record-keeping.

5. What rules govern the sale of therapeutic products to consumers over the internet (including social-media and marketplace platforms)?

The MPL does not establish a standalone regime governing the online sale of therapeutic products to consumers. However, medical products continue to require marketing authorisation from the EDE prior to circulation in the UAE, and sales to consumers remain restricted through licensed pharmaceutical establishments. Prescription medical products cannot be sold by non-pharmaceutical establishments.

Accordingly, online sale of therapeutic products is only permitted when conducted by, or directly linked to, a duly licensed pharmacy or authorised healthcare establishment, and subject to approval and supervision by the relevant Local Healthcare Regulator.

Sales through unlicensed channels not linked to a licensed pharmacy or authorised establishment, constitute unauthorised distribution and may give rise to administrative and criminal sanctions.

The online supply of medical devices is also regulated and depends on the medical device risk classification and intended use. Higher-risk medical devices are restricted to professional or institutional channels and lower-risk medical devices are potentially eligible for consumer supply, subject to EDE approval.

IMPORT

6. What is the import-control framework for therapeutic products (eg, import licences, product registration or listing prerequisites, customs classification, tariff rates, national or regional exemptions, and routine or risk-based border inspections)?

Medical products may not be imported into the UAE without obtaining marketing authorisation from the EDE. They may only be imported by an entity licensed by the EDE for the relevant activity, typically a licensed medical warehouse holding import authorisation. Importation by entities which do not hold the requisite EDE establishment licence and import authorisation is not permitted.

Each import shipment requires a specific permit or approval from the EDE. Import permits typically require: (1) valid marketing authorisation or applicable exemption; (2) licensed applicant entity; and (3) satisfaction of technical and operational conditions specified by the EDE.

Imported shipments remain subject to routine or risk-based inspection by the EDE, and the EDE may restrict or ban import of specific medical products where public health risks exist.

Failure to comply with import prerequisites may result in refusal of clearance, seizure of products, or regulatory enforcement action including administrative sanctions, fines, licence suspension or cancellation, and criminal penalties.

Customs clearance and duties fall under the UAE's general customs framework rather than the EDE regulatory regime. The MPL does not establish product-specific tariff rates for therapeutic products.

7. To what extent may consumers import therapeutic products for personal use (whether by taking the products across the border or receiving them by mail), and what quantitative limits, prescription requirements, customs declarations, duties, or other restrictions apply?

The MPL specifically provides for personal-use imports of medical products and delegates detailed implementation to the MPL Executive Regulations (which have not yet been issued).

Nevertheless, personal-use imports are currently permitted and regulated through operational services administered by the EDE, with MOHAP continuing to administer certain legacy services during the regulatory transition period. Both the EDE and MOHAP operate electronic service platforms which allow UAE residents and travellers to obtain permits to import medical products for personal use, including where products are carried across the border or received by mail or courier.

For narcotics and psychotropic substances (Controlled Materials and Products), UAE residents and travellers may import quantities of up to three months' supply for personal medical use, subject to obtaining prior electronic approval from the EDE through its online portal or smart application.

For prescription medical products that are not controlled materials and products, UAE residents and travellers may import quantities sufficient for personal medical use without prior approval from the EDE, where such products are carried into the UAE, provided they are supported by appropriate documentation, including a valid prescription and, where applicable, a medical report, and subject to the applicable quantitative limits described below.

Quantitative limits apply to prescription medical products. Quantities are assessed by reference to the patient's medical needs, subject to a maximum of up to six months' supply. In this context, 'supply' is determined primarily by reference to the prescribed dosage and treatment duration set out in the supporting prescription or medical report, rather than solely by reference to pack size. The applicable quantity is therefore the lower of: (1) the amount required; and (2) the relevant maximum limit. In practice, for travellers, the assessment of personal-use quantities may take into account the duration of their stay in the UAE, whereas for UAE residents the assessment is typically made by reference to ongoing personal medical need, in each case subject to the applicable maximum limit.

Where medical products (including prescription medical products) are imported by shipment or otherwise require regulatory clearance (including where quantities exceed standard personal-use limits), an application may be required to be submitted through the EDE electronic system. For controlled materials and products, such approval is required in all cases.

For non-prescription medical products, UAE residents and travellers may generally bring such products into the UAE for personal use without prior approval from the EDE, provided that the products are not classified as controlled or otherwise restricted and are not imported for commercial purposes. No fixed quantitative limits are prescribed for non-prescription products. In practice, 'reasonable quantities' are assessed on a case-by-case basis by customs authorities, taking into account factors such as the nature of the product, pack size, and whether the quantities are consistent with personal use.

The personal-use import regime is primarily designed for pharmaceutical products. Import of medical devices for personal use is more limited and generally restricted to low-risk medical devices, subject to customs and EDE review. Customs duties and tariff treatment, where applicable, are governed by the UAE's general customs framework rather than the MPL.

8. May foreign suppliers ship therapeutic products directly to consumers via e-commerce or mail order, and what local presence, platform registration, verification, or labelling obligations – if any – must they satisfy?

Medical products may not be shipped directly to consumers in the UAE via e-commerce, social media, or mail order, unless the importation and retail supply are carried out by, or through, a licensed pharmaceutical establishment in the UAE. Importation and retail supply of medical products are regulated activities reserved to licensed establishments.

This ban applies regardless of whether the medical products are prescription-only or over-the-counter. It reflects the UAE regulatory model under which consumer access to medical products is mediated through licensed domestic pharmaceutical establishments.

However, the MPL does permit personal-use import for individuals, which is not intended as a channel that foreign suppliers may rely on commercially. A foreign supplier cannot lawfully structure direct-to-consumer sales into the UAE by relying on the personal-use regime, even if shipments are addressed to individuals or labelled as non-commercial.

Where online or electronic supply of medical products is permitted, it must be conducted by or through a licensed pharmaceutical establishment which remains fully responsible for compliance with the MPL and regulations issued by the EDE and Local Healthcare Regulators, including

dispensing, record-keeping, and supervision requirements, platform security, customer identity verification, prescription validation, and delivery and traceability controls.

All medical products supplied to consumers must also comply with UAE labelling and packaging requirements, irrespective of whether supply occurs through physical or electronic channels.

9. How is parallel importation (ie, of products licensed and sold in other jurisdictions) of therapeutic products by businesses regulated, particularly with respect to intellectual property rights, product re-labelling or re-packaging, and requirements to maintain original quality, safety, and traceability?

The parallel importation of medical products is not permitted as an independent commercial distribution channel in the UAE. Medical products may not be imported, distributed, or circulated in the UAE unless they are registered with the EDE and have obtained marketing authorisation. Lawful marketing of a product in another jurisdiction does not, of itself, permit importation into the UAE. Regulatory approval by the EDE through marketing authorisation therefore remains the decisive prerequisite for lawful importation and distribution.

Marketing authorisation is product-specific and linked to a defined authorisation structure, including ongoing obligations relating to pharmacovigilance, safety reporting, and post-market surveillance borne by the marketing authorisation holder.

Labelling and repackaging of medical products must comply with EDE-approved labelling requirements and product information, and all medical oroducts must be integrated with the National Tracking System to ensure end-to-end supply-chain traceability.

While UAE law generally recognises the international exhaustion of trademark rights, this principle does not override the mandatory regulatory requirements of the MPL, with the effect that medical products licensed and sold in other jurisdictions cannot be imported outside the authorised distribution channels established under the UAE regulatory framework.

EXPORT

10. Are there quantitative quotas, permits, or other measures that restrict or condition the export of therapeutic products (eg, to mitigate shortages or address public-health emergencies), and how are such measures administered and enforced?

The export of medical products from the UAE is subject to specific EDE licensing and administrative controls. An entity seeking to export medical products from the UAE must obtain an EDE-issued shipment-specific export permit.

Export permits are generally limited to licensed entities which typically include biobanks, laboratories, medical warehouses, pharmaceutical factories, and other establishments holding import/export authorisation from the EDE.

The EDE may restrict or ban exports if risks to public health exist or if illegal intent is suspected.

Export permits may be cancelled on various grounds including forged or incorrect documentation, safety, quality, or efficacy issues, marketing authorisation deficiencies or cancellation.

The MPL does not specifically establish quantitative export quotas or mandatory local stock-sufficiency requirements. However, export permits are subject to EDE regulatory discretion and may be denied, restricted, suspended or cancelled to protect public health interests or mitigate domestic shortages.

In practice, the EDE applies a risk-based assessment of export applications, taking into account factors such as domestic supply adequacy, public health priorities, and the exporter's regulatory compliance history.

11. Is there any form of 'export-only' or 'dual-labelling' authorisation that permits the manufacture and export of therapeutic products not approved for domestic marketing, and if so, what standards, labelling, or record-keeping obligations apply?

Although the MPL does not explicitly establish a distinct category of 'export-only' or 'dual-labelling' authorisation that permits the manufacture and export of medical products not registered for marketing in the UAE, the MPL does indicate that the MPL Executive Regulations will introduce specific controls and conditions for such export-only arrangements. As such, there is currently no operative 'export-only' marketing authorisation regime in force.

Until such time as the MPL Executive Regulations are issued, export of medical products is governed by the EDE's export permit regime, and the EDE retains discretion to permit or restrict export based on public health considerations and regulatory compliance. To obtain EDE approval for export, the entity must apply for an export permit. The conditions for granting export permits include a valid marketing authorisation or an applicable statutory exemption, licensed applicant status, and satisfaction of technical and operational conditions.

When export permission is granted, the exporting establishment remains subject to the EDE's quality-control and traceability framework. Medical products exported from the UAE must be manufactured in EDE-licensed facilities in conformity with the MPL's regulations and applicable Good Manufacturing Practice standards.

Export-specific labelling, if different from domestic labelling requirements, must be managed through the exporting manufacturer's approved quality system and EDE-approved procedures. Product identity, batch and serial information, and documentary traceability must remain intact and auditable through EDE-controlled quality and traceability mechanisms.

LABELLING, TRACEABILITY, AND PRODUCT INFORMATION

12. What local language labelling, patient information, unique device identification, serialisation, anti-counterfeiting, or traceability requirements must be met before imported therapeutic products may circulate domestically or before therapeutic products may be exported?

Prior to circulation or marketing of medical products in the UAE, the product must be registered with and authorised by the EDE. No medical product may be marketed in the UAE unless information is provided on internal and external packaging and paper or electronic leaflets.

Leaflets accompanying medical products must be in Arabic and English, unless the EDE decides otherwise for specific products or categories. medical products must comply with EDE labelling guidelines.

Free samples of medical products distributed to healthcare professionals must be stamped with the phrase 'Free Medical Sample Not for Sale' in Arabic and English. The EDE-approved public selling price must be attached to the external packaging of all medical products before sale. The name or mark of the importer or manufacturer must be clearly identified on product packaging.

The EDE has established the National Tracking System to track and code medical products from manufacturer to end user with the goal of ensuring safety, authenticity, anti-counterfeiting, and the prevention of counterfeit products. All licensed pharmaceutical establishments must integrate with and comply with the National Tracking System requirements.

For medical products intended for export, product identity, batch and serial information, and documentary traceability must remain intact and auditable through the EDE-controlled quality and traceability mechanisms, including the National Tracking System.

While the MPL does not specifically mandate Unique Device Identification (UDI) requirements for medical devices at statutory level, the EDE applies binding medical device-specific identification, registration and tracking requirements through its administrative procedures, electronic systems and risk-based regulatory guidance, which was initiated pursuant to Cabinet Resolution No. 59 of 2020 on Drug Tracking and Monitoring.

Although not set out in primary legislation, these requirements operate as mandatory conditions of product registration, importation and market access, and are therefore legally binding in practice. Compliance is typically assessed through the EDE's registration and tracking platforms (including the National Tracking System) and associated guidance and circulars.

Non-compliance may result in refusal or suspension of product registration, restrictions on importation or distribution, and other regulatory enforcement actions, including product recall or withdrawal from the market.

PRICING, REIMBURSEMENT, AND MARKET ACCESS

13. Are there any price-control, reimbursement, public procurement, or stock/supply-obligation regimes that (while not trade measures per se) materially influence the distribution channels or availability of therapeutic products?

The MPL establishes price-control mechanisms for medical products marketed in the UAE. Medical products must have a specific price determined by the EDE before they may be marketed in the UAE. The public selling price approved by the EDE must be attached to the external packaging of medical products before sale.

Licensed pharmaceutical establishments are explicitly banned from selling medical products at prices exceeding those set by the EDE, and from offering discounts or price reductions on medical products below those set by the EDE in the retail market. As such, the EDE-set price constitutes the mandatory fixed retail price.

The EDE maintains a national database that includes pricing information for registered medical products. The EDE operates an online portal and electronic systems through which marketing authorisation holders submit pricing information, support pricing decisions, and access approved price listings.

Local Healthcare Regulators enforce pricing compliance through inspections and audits.

The MPL does not establish a centralised public procurement or reimbursement authority comparable to those in certain other jurisdictions. Procurement of medical products by government healthcare institutions is governed by applicable federal and Emirate-level public procurement laws and regulations, in addition to the regulatory requirements imposed by the MPL. In practice, public healthcare institutions typically procure medical products through formulary listing and tender processes, with purchasing decisions and volumes determined at the level of the relevant federal or Emirate authority.

The EDE enforces supply and availability obligations on licensed pharmaceutical establishments. Medical warehouses and other licensed establishments are required to maintain appropriate levels of supply of medical products and to notify the EDE of anticipated shortages.

Taken together, pricing controls, procurement practices and supply-obligation requirements materially influence market access, distributor margins, and the availability of medical products across public and private healthcare channels in the UAE.

ENFORCEMENT, COMPLIANCE, AND RECENT DEVELOPMENTS

14. What investigative powers, sanctions, and remedial measures (administrative, civil, or criminal) are available to regulators when they detect non-compliance with trade and distribution rules for therapeutic products, and how are these powers used in practice?

Non-compliance with trade and distribution rules for medical products is addressed through a comprehensive enforcement framework combining administrative, civil, and criminal measures exercised principally by the EDE, and, at Emirate level, by the Local Healthcare Regulators.

From an investigative perspective, the EDE has statutory authority to conduct announced and unannounced inspections of licensed pharmaceutical establishments, medical warehouses, pharmacies, and points of sale to review records, inspect facilities, examine products, and collect samples. The EDE may seize medical products suspected of non-compliance, including unregistered, falsified, counterfeit, or improperly labelled products.

Local Healthcare Regulators also conduct inspections and enforcement activities at the Emirate level. For example, DHA operates a Drug Control Section which conducts scheduled and unannounced inspections of licensed pharmacies in Dubai. DHA inspectors may request documentation, review records, inspect facilities and storage areas, collect product samples, and issue electronic inspection reports specifying compliance status and recommendations. Non-compliance findings may result in recommendations for corrective action.

The EDE operates the National Tracking System to ensure product authenticity, prevent counterfeiting, and monitor the supply chain. The EDE maintains comprehensive databases covering registered medical products, licensed establishments, licensed professionals, and pricing information.

At the administrative level, the EDE may impose a range of corrective and punitive measures for violations of the MPL, including warnings, fines, licence suspension or cancellation, product recalls, and suspension of import or export permissions.

For serious violations, such as unlicensed import, export, manufacture or sale of medical products, falsification, or conduct posing a public-health risk, the MPL provides for criminal liability, enforced through referral to the public prosecution. Penalties include fines and imprisonment. Additional enforcement measures include confiscation and destruction of non-compliant medical products at the violator's expense.

Civil liability may also arise in parallel, including private claims for damages caused by regulatory breaches or product-related harm.

Local Healthcare Regulators may issue Emirate-level administrative enforcement actions consistent with federal MPL requirements. For example, DHA may issue warnings, impose fines, suspend licences, or initiate licence cancellation proceedings based on inspection findings and violations of DHA and federal regulations.

15. Is there recent case law, legislative or policy developments, noteworthy enforcement trends, or anticipated reforms that may significantly alter the regulation of trade, distribution, or cross-border movement of therapeutic products in the future?

The most significant recent development is the enactment of the MPL which introduced key reforms including the establishment of the EDE as the primary federal regulatory authority and multiple marketing authorisation pathways: standard, conditional, fast-track, and emergency use.

The MPL Executive Regulations remain pending. Once issued, they are expected to provide further operational detail on licensing, distribution controls, inspections and enforcement, and will be central to the practical implementation of the MPL. In particular, it is anticipated that they will clarify how certain new statutory concepts introduced by the MPL will be applied in practice.

One such example is the MPL's requirement for the appointment of more than one importer for certain medical products. which will need to be reconciled with the UAE Commercial Agencies Law which currently permits the registration of only a single commercial agent per medical product.

Publicly available UAE case law relating to trade and distribution of therapeutic products remains extremely limited. In practice, regulatory interpretation and enforcement trends develop through regulatory decisions rather than report judicial judgments.

More broadly, the UAE healthcare policy continues to prioritise innovation and digital health initiatives, including the use of AI in areas such as diagnostics, genomics and drug discovery. While not trade measures per se, these initiatives are expected to influence future regulatory approaches to market access, data use and product development.