Guide on the UAE's Evolving Pharma Regulations: Key Changes to Federal Law Number 38 of 2024

New Era of Pharmaceutical Regulation in the UAE: Changes to Federal Law Number 38 of 2024

For quite a while now, the United Arab Emirates has led in health care and pharmaceutical innovations across the Middle East. The UAE government passed Federal Law No. 38 of 2024, which became effective on January 2, 2025, to uphold its status as the regional leader in the pharmaceutical sector, thereby adhering to strict guidelines regarding patient safety. This law effectively replaces Federal Law No. 8 of 2019 and profoundly raises the bar in terms of legislation related to pharmaceuticals, pharmacists, and pharmaceutical institutions in the country.

The law will enhance the safety of patients, oversight from regulators, and efficiency in the market with encouragement for innovation and investment in the pharma sector of the UAE. Some of the main provisions include the establishment of EDE, new nomenclature for medical products, enhanced marketing approval scheme, and certain intellectual property protection measures. Moreover, it further introduces stricter pharmacovigilance standards, widened compliance responsibility, and severe penalties in case of non-compliance. The article explains the salient provisions, compliance obligations, and implications of this law on the pharmaceutical sector of the UAE in detail.

Objectives of Federal Law No. 38 of 2024

This law is an essential step for the UAE toward achieving its greater vision of being a hub in the pharmaceutical and healthcare sectors. These objectives include the following:

i. Pharmaceutical Regulation Enhancement

Building a modern, transparent regulatory structure that will maintain market integrity and protect patients.

ii. Pharmaceutical Security

Guarantee all pharmaceutical products adhere to the required standards from production through supply to consumers in respect of their quality and safety.

iii. Encourage Investment and Innovation

Promote Foreign Direct Investment and Pharmaceutical Innovation, domestic through IP Protection

iv. Regulation of Pharmaceuticals Harmoization

The regulatory regime in place to standardize and ensure harmony of pharmaceutical rules within the international frameworks and models in existence across the world. It aims to comply with best global practice by other health-related entities including WHO, US FDA, EMA.

v. Improve Public Health Outcome

Ensure drugs and medicines and medical products entering the UAE market adhere to rigorous standards of safety, efficacy, and quality.

Main Provisions of Federal Law No. 38 of 2024

I. Establishment of Emirates Drug Establishment (EDE)

Establishment of Emirates Drug Establishment or EDE marks the most monumental reforms under this new law where the pharmaceutical regulation is being brought together

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"The good physician treats the disease; the great physician treats the patient who has the disease."
– William Osler

the pharmaceutical regulation is being brought together into one place. The Emirates Drug Establishment EDE now administers:

i. Approval and registration of pharmaceutical products.

ii. Pharmacovigilance and monitoring of adverse events.

iii. Market surveillance to ensure quality standards.

iv. Development of the UAE Pharmacopeia, a national reference for drug quality and safety.

Extended Definitions and Scope of Regulated Products

The law expands the classification of medical products, now including:

i. Pharmaceutical drugs and medical devices.

ii. Biological products and gene therapies.

iii. Orphan pharmaceutical products (for rare diseases).

iv. Dietary supplements, cosmetics, and nutraceuticals.

v. Genetically modified organisms (GMOs) used in medicine.

vi. Chemical precursors and controlled drugs for medical purposes.

III. New Marketing Approval System

The marketing approval system has been reformed with:

i. Conditional approvals of treatments of life-threatening conditions

ii. Fast-track approvals for innovative or emergency-use medicines

iii. Toughened standards on the efficacy, quality, and safety of the product.

iv. The pharmaceutical industry has to comply with EDE rules on clinical trials, labeling, and advertisement.

IV. Enhanced Intellectual Property Protection

In order to foster innovation, the law grants greater intellectual property protections, which are:

i. RDP periods for new drug applications.

ii. Exclusivity for innovative medical preparations.

iii. Protection against unfair competition in the pharmaceutical industry.

V. Strengthened Pharmacovigilance and Product Recall

The Act provides for strict post-marketing surveillance, inter alia,

i. Immediate reporting of ADRs.

ii. Periodic pharmacovigilance inspections of manufacturers and distributors.

iii. Product recall of drugs found to be adulterated or hazardous.

iv. In case of violation of these provisions, severe punishment is meted out.

VI. Higher Punishment for Violation

To deter violations, the law imposes tougher penalties, including:

i. Fines up to AED 1 million for pharmaceutical establishments.

ii. Fines up to AED 500,000 for individual practitioners.

iii. License suspension or revocation for repeated offenses.

iv. Criminal liability in cases of severe negligence or fraudulent practices.

Implications for Stakeholders

I. Manufacturers and Distributors

i. Must adapt to new marketing approval processes under the EDE framework.

ii. Required to implement robust pharmacovigilance measures.

iii. Must comply with stricter licensing and inspection standards.

II. Health Care Organizations (Hospitals and Pharmacies)

i. Compliance with new regulations on dispensing, storage, and sales of

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"Medicine is not only a science;
it is also an art. It does not consist of compounding
pills and plasters; it deals with the very processes of life."
– Paracelsus

ii. The clinical pharmacist would play a significant role in patients' care and medication management.

IV. Investors and Inventors

i. Increased protection for intellectual property is likely to inspire more research and development of drugs.

ii. The expedited approval procedure accelerates access of new therapies into the market.

iii. Encouragement for biotechnology companies and pharmaceutical venture capital firms to enter the UAE market

Compliance and Transition Period

To ease the transition, a one-year grace period has been granted to businesses and professionals to adhere to the new enactment. The Cabinet may consider additional extensions, if needed.

Recommended steps for stakeholders:

i. Update the compliance policies of an organization to include the changes that have been incorporated in EDE.

ii. Seek advice of lawyers and consultants to ensure that the changes are appropriately made to the enactment.

iii. Strengthen pharmacovigilance frameworks to comply with post-market surveillance requirements.

iv. Request any licensure updates required within the transition timeframe.

v. Watch for EDE guidance on other updates and timelines for implementation.

Conclusion

Federal Law No. 38 of 2024 represents a new leap in the pharmaceutical industry of the UAE: enhanced safety, improved regulatory effectiveness, and a spur to innovation. With EDE at the top, the pharmaceutical regulation is centralized and streamlined; it will contribute positively to the integrity of the market and to the health of its citizens.

The law positions the UAE as a competitive hub for pharmaceutical research and development while strengthening consumer protections through stricter oversight and enforcement. Stakeholders must proactively align with these new regulatory requirements to ensure continued market access and compliance.

Embracing these changes, pharmaceutical companies, healthcare providers, and innovators can contribute to a safer and more dynamic pharmaceutical ecosystem in the UAE, further solidifying the country's global leadership in medical and pharmaceutical advancements.

"Wherever the art of medicine is loved, there is also a love of humanity."

- Hippocrates

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