

## REGULATION OF THE UAE PHARMACEUTICAL INDUSTRY

31 July 2025

The United Arab Emirates aims to strengthen its position as a leading pharmaceutical hub.

In this regard, the UAE is implementing a more transparent and harmonised regulatory system for the pharmaceutical sector. The new system seeks to ensure a secure and consistent supply of medical products, facilitate a faster market entry of innovative products, advertise, promote products and stimulate scientific development.

One of the key measures contributing to the improvement of regulation in the UAE was the adoption of Federal Law No. 38 of 2024 on the regulation of the circulation of medical products, including medicines and medical equipment, and the activities of pharmacists and pharmaceutical institutions (“**Law No. 38**”).

This alert provides an overview of the main provisions of Law No. 38 and other features of the regulation of the pharmaceutical sector in the UAE.

### 1. Current regulation

Law No. 38 significantly altered the regulation of the pharmaceutical industry in the UAE, replacing Federal Law No. 8 of 2019.

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The main objectives of Law No. 38 include:

- creating a modern and transparent regulatory system of the pharmaceutical industry;
- guaranteeing compliance of pharmaceutical products with quality and safety requirements at all stages;
- incentivising foreign investment and pharmaceutical innovation, including by extending the protection of intellectual property rights;
- establishing a unified regulatory regime in line with international standards, as well as
- ensuring strict criteria for the safety, efficacy, and quality of pharmaceutical and medical products.

## 2. Key changes

### 2.1. Expansion of the list of regulated products and pharmaceutical organisations

Law No. 38 covers not only pharmaceuticals and medical devices, but also biopharmaceuticals, drugs for rare diseases (orphan drugs), biologically active supplements (BAS), cosmetics, products containing genetically modified organisms (GMOs) intended for medical use, chemical precursors, hazardous and toxic substances,

as well as substances intended for both medical and veterinary use.

Law No. 38 also regulates pharmacists and expands the list of organisations subject to the current regulation. The list includes research hubs, laboratories, manufacturing companies, pharmacies, marketing offices, warehouses, and logistics hubs.

In addition, for the first time, the law explicitly covers biobanks — institutions responsible for collecting, storing, and distributing biological samples and information on them<sup>1</sup>.

### 2.2. Formation of the Emirates Drug Establishment ("EDE")

Law No. 38 created the Emirates Drug Establishment ("**EDE**") to replace the Ministry of Health and Prevention ("**MOHAP**") as the main regulator, granting it the authority to issue marketing approvals for product sales<sup>2</sup>, import and export permits<sup>3</sup>, approve product advertisements and promotions<sup>4</sup>, and issue and renew licences for relevant activities (e.g., for conducting research, for manufacturing medical products)<sup>5</sup>.

Its functions also include certification of good practices and organisations<sup>6</sup>, pharmacovigilance<sup>7</sup>, suspension or recall of medical products in case of violations<sup>8</sup>, tracking and coding of medical products<sup>9</sup>, establishing and maintaining the national database for medical products<sup>10</sup>, setting

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<sup>1</sup> Article 2 of the Federal Decree-Law No. (38) of 2024 Governing Medical Products, Pharmacists and Pharmaceutical Establishments ("**Law No. 38**").

<sup>2</sup> Articles 4-17 of the Law No. 38.

<sup>3</sup> Articles 31-33, 52, 63 of the Law No. 38.

<sup>4</sup> Articles 44-47 of the Law No. 38.

<sup>5</sup> Part 7 of the Law No. 38.

<sup>6</sup> Articles 26, 42, 49 of the Law No. 38.

<sup>7</sup> Article 23 of the Law No. 38.

<sup>8</sup> Articles 70, 102, 103 of the Law No. 38.

<sup>9</sup> Article 65 of the Law No. 38.

<sup>10</sup> Articles 65-67 of the Law No. 38.

prices<sup>11</sup>, regulating administrative, disciplinary, and criminal liability<sup>12</sup>.

The EDE is the largest reform under the Law No. 38, consolidating the regulation of the pharmaceutical sector under a single authority.

### 2.3. *A new approach to approving medical products for the UAE market*

Law No. 38 provides for a new approach to approving medical products for the UAE market, which includes:

- conditional marketing authorisation for orphan drugs<sup>13</sup>;
- accelerated approval for emergency drugs and innovative drugs with therapeutic significance<sup>14</sup>;
- enhanced standards of efficacy, quality, and safety<sup>15</sup>.

### 2.4. *Regulation of advertising and promotion of medical products in the UAE*

Within the framework of advertising regulation, Law No. 38:

- prohibits the sale of free promotional samples of medical products<sup>16</sup>;
- prohibits any advertising of medical products without the EDE's approval<sup>17</sup>;
- prohibits advertising to the general public of dangerous chemical

precursors, products or substances intended for human or veterinary use<sup>18</sup>;

- authorises the EDE to prohibit or restrict advertising of certain products, allowing it only for targeted groups. Details will be defined in the bylaws<sup>19</sup>;
- mandates the presence of a registration certificate as well as the indication of risks and side effects of pharmaceutical products. Advertising materials must be truthful and not misleading<sup>20</sup>.

If the above provisions are not complied with, the advertising approval may be withdrawn<sup>21</sup>.

### 2.5. *Enhanced protection of intellectual property*

Law No. 38 provides for protection of intellectual property for innovative drugs and drugs containing at least one new active substance, including those developed in the UAE

and imported from abroad. Details will be defined in the bylaws<sup>22</sup>.

### 2.6. *Pharmacovigilance*

Law No. 38 establishes stricter requirements for pharmacovigilance, including monitoring and reporting instances of adverse drug reactions<sup>23</sup>. EDE is committed to providing information on safety measures related to the use of medical products, as well as serious side effects and other important information<sup>24</sup>.

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<sup>11</sup> Articles 75, 105 of the Law No. 38.

<sup>12</sup> Part 8 of the Law No. 38.

<sup>13</sup> Article 8 of the Law No. 38.

<sup>14</sup> Article 14 of the Law No. 38.

<sup>15</sup> Article 6 of the Law No. 38.

<sup>16</sup> Article 39 of the Law No. 38.

<sup>17</sup> Article 44 of the Law No. 38.

<sup>18</sup> Article 44 of the Law No. 38.

<sup>19</sup> Article 44 of the Law No. 38.

<sup>20</sup> Article 45 of the Law No. 38.

<sup>21</sup> Article 47 of the Law No. 38.

<sup>22</sup> Article 18 of the Law No. 38.

<sup>23</sup> Article 68 of the Law No. 38.

<sup>24</sup> Article 69 of the Law No. 38.

## 2.7. Liability

Law No. 38 increases the penalties for violations of legislation regulating the pharmaceutical industry. It allows the possibility of imposing larger fines, imprisonment, suspension of activities and prohibition from entering the market<sup>25</sup>.

Persons engaged in activities in the pharmaceutical sector in the UAE should take

a year (the transitional period provided for in Law No. 38) to familiarise themselves with the provisions of Law No. 38, review their current compliance practices, and consult with experts.

## 3. Product Traceability

The UAE's pharmaceutical product tracking platform, Tatmeen, was launched in April 2025. Its launch is one step towards establishing a modern and transparent regulatory system for pharmaceutical and healthcare products, in line with the objectives of Law No. 38.

The initiative aims to combat counterfeiting, illegal imports, and substandard pharmaceutical products, improve the management of recalls and removal of expired medicines and increasing transparency in the pharmaceutical chain from manufacturer to end user.

## 4. Infrastructural and regulatory support of the biotechnological sector

Biotechnology and pharmaceutical companies in the UAE's free economic zones are subject to regulations that allow a more flexible business environment.

The majority of Dubai biotech companies are located in two free economic zones: Dubai Biotechnology and Research Park (DuBiotech) and Jebel Ali Free Zone (JAFZA).

Abu Dhabi, the UAE's biotech hub, is home to the Life Sciences Cluster in Masdar City Free Economic Zone, biotechnology and life sciences centre supported by the Abu Dhabi Department of Health (DoH) and the Abu Dhabi Investment Authority.

The HELM (Health, Endurance, Longevity, Medicine) Cluster was also launched in Masdar City. This is an integrated research, development and manufacturing platform for biotechnology, medicine, and digital health. The project paves the way for the development of pharmaceutical manufacturing, application of AI and attracting global leaders in advanced technologies and genomics<sup>26</sup>. Abu Dhabi is also home to the Khalifa Economic Zones of Abu Dhabi (KEZAD).

As free zones, DuBiotech, JAFZA, Masdar City, and KEZAD offer benefits such as:

- simplified registration process and regulatory regime;
- tax-free environment (with certain exceptions);
- favourable business environment, as well as
- access to a vast network of global partners and investors.

More than 15 global leaders in biotechnology, such as Johnson & Johnson, GSK, Novartis, Sanofi, Roche, and AstraZeneca, are already represented in the UAE's free economic zones.

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<sup>25</sup> Part 8 of the Law No. 38.

<sup>26</sup>The website of HELM can be accessed via [link](#).

## 5. Conclusion

The enactment of Law No. 38 establishes a solid foundation for the growth of the pharmaceutical sector, further enhancing the UAE's appeal as a jurisdiction for investment and R&D.

The most significant reform under Law No. 38 is the creation of the Emirates Drug Establishment (EDE) and the subsequent strengthening of controls over the safety, efficacy, and quality of medical and pharmaceutical products.

The introduction of accelerated marketing approval procedures and intellectual property protection mechanisms facilitates the entry of innovative medicines into the market.

In addition, advertising and pharmacovigilance controls have been significantly strengthened, increasing transparency in the regulation of the UAE's pharmaceutical industry.

Regulation in many of the UAE's free zones is aimed at supporting pharmaceutical companies and developing biotechnology.

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White Square team is ready to provide necessary assistance with projects related to the UAE pharmaceutical sector, along with tailored advice on all matters relevant to your business needs.



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