

## REGULATION OF THE PHARMACEUTICAL INDUSTRY IN SAUDI ARABIA

14 November 2025

Saudi Arabia (the “**Kingdom**”) is seeking to become a leader in the field of pharmaceuticals and biotechnology, including through the modernization of regulation, creation of favourable conditions for investors, and active development of scientific and technological infrastructure.

The main act regulating the pharmaceutical industry in the Kingdom is the Law of Pharmaceutical and Herbal Establishments and Preparations (the “**Law**”), issued in accordance with Royal Decree No. M/108 of April 15, 2020.

This alert reflects the current regulation of the pharmaceutical industry and provides an overview of the current legal and investment climate in the Kingdom's pharmaceutical industry.

### 1. Current regulations

The law repealed the previous Law of July 18, 2004, “Of Pharmaceutical and Herbal Establishments and Preparations” and modernized the legal framework governing the manufacture, registration, distribution, and advertising of pharmaceutical and herbal products, as well as the activities of scientific representatives.

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The main objectives of the current regulation are:

- Comprehensive regulation of the circulation of pharmaceutical products and herbal preparations;
- Ensuring the safety, efficacy, and quality of pharmaceutical products;
- Developing the pharmaceutical industry in accordance with international standards;
- Creating a more open and flexible environment for foreign investors and specialists;
- Attracting foreign technology, expertise, and capital to the pharmaceutical sector;
- Protecting national interests and raising professional standards in the industry.

## 2. Key changes

### 1) *Opportunities for foreign investors*

Previously, ownership of certain types of pharmaceutical businesses, such as medical consultation centres, pharmaceutical research and analysis centres, and pharmaceutical wholesale warehouses, was restricted to citizens of the Kingdom.<sup>1</sup> As a result, foreign investors were unable to invest directly in these types of businesses and, in some cases, attempted to gain access to such enterprises through informal agreements, creating serious legal and financial risks for the business.<sup>2</sup>

The new Law, in turn,<sup>3</sup> removed previous restrictions on foreign ownership, allowing foreign investors to directly own and manage these types of pharmaceutical companies in the Kingdom.

### 2) *Management conditions for foreign persons*

The new Law also abolished several

"localization" requirements that were contained in the previous pharmaceutical law. Previously, one of the mandatory conditions for managing pharmaceutical wholesale warehouses<sup>4</sup>, as well as medical consulting and analytical centres<sup>5</sup>, was the presence of a licensed pharmacist-manager who was a citizen of the Kingdom. Under the new regulations, the requirement for a licensed pharmacist remains, but the requirement for Saudi citizenship no longer applies.<sup>6</sup>

Despite this, the requirement of the Kingdom citizenship remains for the appointment of a technical manager at a manufacturing facility.<sup>7</sup>

In addition, Royal Decree No. M/195 of March 3, 2025 ("**Decree No. 195**") officially allowed foreign ownership of retail pharmacies. This measure removed the remaining restrictions and opened the retail segment of pharmaceutical market to direct foreign investment. It is expected that this change will contribute to the increase of foreign interest in establishing and acquiring pharmacy chains in the Kingdom. Decree No. 195 will remain in effect until a new comprehensive healthcare law is adopted. Notably, such law is expected to maintain the current level of liberalization for foreign investors.<sup>8</sup>

### 3) *Regulatory Authority*

The new Law has transferred the authority to regulate the pharmaceutical sector to the Saudi Food and Drug Authority ("**SFDA**"). The SFDA is now the primary regulatory authority that is responsible for overseeing, licensing and registering pharmaceutical products<sup>9</sup>, inspecting and controlling their quality<sup>10</sup>, reviewing pharmaceutical prices<sup>11</sup>,

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<sup>1</sup> Article 3 of the Law of July 18, 2004, "Of Pharmaceutical and Herbal Establishments and Preparations" ("Old Law"). Access via [link](#).

<sup>2</sup> Opening of pharmaceutical companies to foreign investment. Access via [link](#).

<sup>3</sup> Articles 3–5 of the Law of April 15, 2020, "Of Pharmaceutical and Herbal Establishments and Preparations" ("Law"). Access via [link](#).

<sup>4</sup> Article 4 of the Old Law.

<sup>5</sup> Article 3 of the Old Law.

<sup>6</sup> Articles 3-4 of the Law.

<sup>7</sup> Article 5 of the Law.

<sup>8</sup> Saudi Arabia allows foreign investment in pharmacies. Access via [link](#).

<sup>9</sup> Articles 2, 17 of the Law.

<sup>10</sup> Articles 16, 33 of the Law.

<sup>11</sup> Article 11 of the Law.

issuing export permits<sup>12</sup> and penalties<sup>13</sup>, and conducting other pharmaceutical activities in the Kingdom.

#### 4) Advertising

Advertising and promotion of pharmaceutical and herbal products is permitted only if carried out by a licensed pharmacist who is a citizen of the Kingdom, working full-time with a valid pharmaceutical license<sup>14</sup>.

However, in the event of a shortage of qualified pharmacists who are citizens of the Kingdom, the citizenship requirement may be waived<sup>15</sup>.

In addition, advertising of pharmaceutical and herbal products is regulated by the rules established by the new Law.<sup>16</sup> Prescription drugs may only be advertised in scientific publications and at events for medical professionals, in compliance with the requirements and only after approval by the SFDA.<sup>17</sup> Over-the-counter drugs may be promoted in the media, but also only after obtaining permission from the SFDA. Scientific lectures and information campaigns (including those for a general audience) also require prior approval from the SFDA.

The detailed regulations regarding the advertisement and marketing of pharmaceutical products, herbal products and non-prescriptive health products are provided by the Guide for the Rules and Procedures for the Marketing Advertising Pharmaceutical and Herbal Products.<sup>18</sup> Accordingly, the drug must be approved by SFDA prior to any advertisement, as well as registered or listed in the registry. However,

in certain cases, the SFDA has the right to make an exception and allow the promotion of unregistered *innovative* drugs, but only within the framework of conferences and symposiums intended for medical professionals.

Notably, medical devices in the Kingdom are subject to different laws and regulations, i.e., Medical Devices Law<sup>19</sup>, Medical Devices Regulations<sup>20</sup>, Requirements for Advertisement Approval and Launching Awareness and Charity Campaigns for Medical Devices (the “**Requirements**”)<sup>21</sup>. According to the Requirements, any advertisement regarding the use of medical devices must be licensed by SFDA and has Medical Device Marketing Approval (“**MDMA**”). The promoters must avoid spreading any misleading information about medical devices’ performance, and must provide relevant details compatible with user’s specific needs. Additionally, the sales representatives shall possess sufficient knowledge about the medical devices they promote. The advertisement can be targeted towards both general public and health practitioners.

#### 5) Import, export, and retail trade

Previously, the export and import of pharmaceutical products was only permitted with the consent of the Ministry of Health<sup>22</sup>, and retail sales were only permitted through pharmacies and specialized herbal medicine outlets<sup>23</sup>. The new Law redistributes these powers, transferring control over imports and exports to the SFDA.<sup>24</sup> In addition, it gives the SFDA's director general the right

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<sup>12</sup> Article 22 of the Law.

<sup>13</sup> Article 36 of the Law.

<sup>14</sup> Article 10 of the Law.

<sup>15</sup> Article 10 of the Law.

<sup>16</sup> Article 31 of the Implementing Regulations of the Law on Pharmaceutical and Herbal Establishments and Products. Access via [the link](#).

<sup>17</sup> Article 31 of the Implementing Regulations of the Law on Pharmaceutical and Herbal Establishments and Products. Access via [the link](#).

<sup>18</sup> The Guide for the Rules and Procedures for the Marketing Advertising Pharmaceutical and Herbal Products in Saudi Arabia.

<sup>19</sup> The Law of February 18, 2021 “Medical Devices and Supplies”. Access via [link](#).

<sup>20</sup> The Implementing Regulations of the Medical Devices and Products Law (the “Medical Devices Regulations”). Access via [link](#).

<sup>21</sup> Requirements of June 15, 2022, for Advertisement Approval and Launching Awareness and Charity Campaigns for Medical Devices issued by the Saudi Food and Drug Authority.

<sup>22</sup> Articles 25-26 of the Old Law.

<sup>23</sup> Article 16 of the Old Law.

<sup>24</sup> Articles 22-23 of the Law.

to authorize the sale of certain drugs outside pharmacies in exceptional cases<sup>25</sup>.

#### 6) *Responsibility*

The new Law has significantly tightened the system of sanctions. For certain violations, including counterfeiting, illegal sale of unregistered or expired drugs, the law provides for fines of up to \$1,333,000, temporary closure for up to 180 days, revocation of licenses, and in some cases even criminal liability of up to 10 years' imprisonment.<sup>26</sup> In the case of a repeated violations, the fine and closure period may be doubled. The SFDA has also been given the authority to impose administrative fines based on a table of violation classifications<sup>27</sup>.

#### 7) *Pharmaceutical supervision*

Pharmacovigilance in the Kingdom is also regulated by the SFDA and includes a comprehensive system for monitoring the safety of pharmaceutical and herbal products. The country has a Good Pharmacovigilance Practice (“GVP”) guideline in place, which sets standards and requirements for ensuring the safety, efficacy, and quality of medicines at all stages, from development to post-registration monitoring and advertising, in line with international practices.<sup>28</sup> Each company is required to have a local pharmacovigilance system (“PSSF”) that complements the global system (“PSMF”), as well as to appoint a qualified person responsible for pharmacovigilance (“QPPV”) who is responsible for managing adverse reactions and interacting with the SFDA<sup>29</sup>.

Saudi Vigilance online platform is available to healthcare professionals and the general public for reporting adverse reactions<sup>30</sup>.

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<sup>25</sup> Articles 14, 26 of the Law.

<sup>26</sup> Article 35 of the Law.

<sup>27</sup> Article 36 of the Law.

<sup>28</sup> Guidance on Good Pharmacovigilance Practices. Access via [link](#).

### 3. Infrastructure support for biotechnology

The Kingdom is not only developing regulations for the pharmaceutical industry but is also actively developing the infrastructure of biotechnology sector as part of the Saudi Vision 2030 strategy<sup>31</sup>.

The infrastructure includes, but is not limited to:

#### ▪ **Saudi Biotechnology Accelerator**

Saudi Biotechnology Accelerator is an international accelerator launched by the Ministry of Health in May 2025 to support innovation in biotechnology, pharmaceuticals, medical technology, and software. The accelerator helps startups with training, asset selection and transfer, clinical trials, registration and market entry, and contributes to the formation of an ecosystem, the development of clinical trial infrastructure, and the attraction of investments<sup>32</sup>.

#### ▪ **King Abdullah International Medical Research Center (“KAIMRC”)**

**KAIMRC** is a leading biomedical research centre. The centre transforms laboratory results into practical medical solutions, implements large-scale projects (such as Saudi Biobank and Cord Blood Bank), and collaborates with international biopharmaceutical companies.

#### ▪ **King Abdulaziz City for Science and Technology (“KACST”)**

KACST is responsible for creating infrastructure to support scientific research in the Kingdom, including grant management, organizing communication networks and databases, and conducting applied research in various institutes, such as energy, space, computer technology, nuclear energy,

<sup>29</sup> Requirements for pharmacovigilance and the Qualified Person Responsible for Pharmacovigilance in Saudi Arabia. Access via [link](#).

<sup>30</sup> Saudi Vigilance System. Access via [link](#).

<sup>31</sup> Saudi Vision 2030. Access via [link](#).

<sup>32</sup> Saudi Biotechnology Accelerator. Access via [link](#).

petrochemicals, and natural resources.

#### 4. Conclusion

Current regulations allow for foreign participation in the pharmaceutical business. The law has opened up access to direct foreign investment in sectors such as

- medical consultation centers;
- analytical centres for research on pharmaceuticals;
- pharmaceutical wholesale warehouses;
- and, from March 2025, retail trade in pharmaceuticals (including pharmacy chains).

The regulations provide for the appointment of foreign specialists to management positions.

Thus, the measures adopted create a basis for attracting foreign investment and the direct participation of foreign investors in the pharmaceutical business in the Kingdom.

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The White Square team is ready to provide the necessary assistance in projects related to the Kingdom's pharmaceutical sector, as well as to advise on all issues, considering the needs of your business.



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