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Pharmaceutical Businesses Opening for Foreign Investment

On 15 April 2020, the Cabinet of the Kingdom of Saudi Arabia ("Saudi Arabia") issued a resolution approving the Pharmaceutical and Herbal Establishments and Substances Regulation (the **New Pharmaceutical Law**), providing a liberalization on the ability of foreign nationals or companies to directly own certain pharmaceutical businesses in Saudi Arabia. The New Pharmaceutical Law was enacted on 16 April 2020 pursuant to Royal Decree number (M/108) of 2020.

The New Pharmaceutical Law repeals and replaces the Pharmaceutical Establishments and Substances Regulation which was enacted in 2004 (the **Old Pharmaceutical Law**).¹ While this article will compare certain aspects under the Old Pharmaceutical Law and the New Pharmaceutical Law, the primary purpose of this article is to discuss certain changes relating to foreign ownership.

RESTRICTIONS ON FOREIGN OWNERSHIP

Under the Old Pharmaceutical Law, the ownership of certain pharmaceutical businesses including medicinal consultation and pharmaceutical-substance analytical centres and pharmaceutical wholesale warehouses (the **Pharmaceutical Businesses**), was strictly limited to Saudi nationals. As a result of such restriction, foreign investors were unable to directly invest in any of these Pharmaceutical Businesses. Historically, foreign investors had indirect investments in Pharmaceutical Businesses through side agreements or schemes or arrangements with local Saudi Arabian nationals. Such arrangements while not uncommon in Saudi Arabia, are illegal and impose significant risks on the foreign investor's interests in the business.

Under the New Pharmaceutical Law, the restrictions on foreign ownership of certain Pharmaceutical Businesses have been removed, consequently allowing foreign investors to directly own any of the specified Pharmaceutical Businesses in Saudi Arabia.

As a result of the regulatory changes introduced under the New Pharmaceutical Law, many of the existing arrangements will potentially terminate and we expect foreign investors will restructure their business

operations in Saudi Arabia, in accordance with the New Pharmaceutical Law. However, foreign investors must ensure that any such restructuring or termination of any such arrangement is done in accordance with any specific contractual arrangements and in compliance with Saudi Arabian law:

LOWER “LOCALIZATION” REQUIREMENTS

In addition to permitting foreign ownership of Pharmaceutical Businesses, the New Pharmaceutical Law dispensed with certain “localization” requirements, which were required under the Old Pharmaceutical Law. For example, the Old Pharmaceutical Law required pharmaceutical wholesale warehouses to be managed by a licensed pharmacist who is a Saudi Arabian national. Such requirement no longer exists under the New Pharmaceutical Law.

Despite the foregoing, the New Pharmaceutical Law requires that pharmaceutical and herbal manufacturing plants operating in the KSA to have a licensed scientific office, and that the manufacturing plant and the scientific office be managed by a pharmacist who is a Saudi Arabian national. Moreover, the New Pharmaceutical Law limits the promotion and the introduction of pharmaceutical and herbal substances in the KSA to Saudi nationals.² These “localisation” requirements have been retained from the Old Pharmaceutical Law.

The table below compares the foreign ownership restrictions and “localization” requirements under the Old Pharmaceutical Law and the New Pharmaceutical Law:

Pharmaceutical Business	Old Pharmaceutical Law	New Pharmaceutical Law
Pharmaceutical Wholesale Warehouses	Must be owned and managed by a Saudi pharmacist	May be 100% foreign owned and managed
Pharmaceutical and Herbal Manufacturing Plant	Technical manager must be a Saudi pharmacist	Technical manager must be a Saudi pharmacist
Medicinal Consultation and Analytical Centres	Must be owned and managed by a Saudi pharmacist	May be 100% foreign owned and managed
Promotion and Introduction of pharmaceutical and herbal products	Limited to Saudi pharmacist	Limited to Saudi Pharmacist
Scientific Office	Must be managed by a Saudi national	Must be managed by a Saudi national

PHARMACIES AND HERBAL SUBSTANCE SALE STORES

Notwithstanding the regulatory changes under the New Pharmaceutical Law and the proposed foreign ownership exemptions, the New Pharmaceutical Law excluded pharmacies and herbal substance sale stores from its scope of application. As such, ownership of these establishments is yet, legally speaking, still limited to Saudi nationals. Nonetheless, we understand that the KSA Ministry of Health, has occasionally permitted, foreign ownership of pharmacies and herbal substance sale stores outside the six largest cities in the KSA on a case-by-case basis³. The intention for this exemption is to promote foreign investment into rural, under-developed areas in the KSA. As set out above, a new regulation is anticipated in respect of pharmacies and herbal substance sale stores. It is yet to be seen whether foreign ownership of these establishments will be permitted under the anticipated regulation.

The changes introduced under the New Pharmaceutical Law are exciting and welcomed. Foreign investors should consider how to potentially benefit from these changes. We will provide a further update once the regulation in respect of pharmacies and herbal substance sale stores is issued.



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¹ According to the Cabinet resolution approving the New Pharmaceutical Law, pharmacies and herbal substance sale stores remain subject to the Old Pharmaceutical Law. A specific regulation in respect of pharmacies and herbal substance sale stores is anticipated.

² The New Pharmaceutical Law entitles the Chairman of the Saudi Food and Drugs Authority to waive this requirement if there was a shortage of Saudi pharmacists. Under the Old Pharmaceutical Law, the Minister of Health had this authority.

³ Riyadh, Jeddah, the Holy City of Mecca, the Holy City of Medina, Al-Ahsa and Ta'if.