Licensing pharmaceutical establishments in Jordan

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The healthcare and pharmaceutical industries in Jordan have been a focal point economically considering the presence of several multi-national pharmaceutical companies that are based in the country. This required the Jordanian government to establish a robust legislation environment for companies to be well regulated in order to maximise quality assurance and reduce any fraudulent activity. The governmental authority responsible for regulating the said industries are the Jordanian Food and Drug Administration (the 'JFDA') and in turn the Ministry of Health (the 'MOH').

In recent years, Jordan has emerged as a key exporter of medicine and pharmaceuticals. This demanded the relevant authorities to revisit the basis for licensing the entities in the sector in order to establish a well organised regime for the same. The New Regulation for Licensing Pharmaceutical Establishments, No. 162 for the year 2019 ('New Regulation') came into effect once it was issued in the Official Gazette at the end of 2019.

The transportation, possession, distribution, sale, gifting, donation, purchasing, importing, and/or using pharmaceutical products and medication in Jordan is only permitted by companies holding a duly valid licence and registration from the MOH following approval of the Minister of Health. The said licence and approval can be granted to pharmaceutical manufacturers, pharmaceutical warehouses, pharmacies, and pharmaceutical research and development companies ('Pharmaceutical Establishments'). Additionally, it is not permitted to circulate or sell any medication or pharmaceutical products without registering the final form and obtaining an approval containing the permitted pricing of the same at the JFDA.

This article shall focus on highlighting the main requirements for registering a Pharmaceutical Establishment and obtaining an approval for the same from the competent authorities.

Pharmaceutical Establishment licensing

It is worth noting that an application to register a Pharmaceutical Establishment must be submitted by a person who possesses a university degree in pharmaceutical studies from an accredited university, and who is registered as a pharmacist at the Jordanian Pharmacist Association ('JPA') and duly licensed to practise the profession pursuant to the Pharmacy and Pharmaceuticals Law (the 'Licensed Pharmacist'), with the exception of pharmaceutical manufacturers that have a separate licensing regime as outlined below.

Pursuant to the New Regulation, the Licensed Pharmacist must submit the application to the JFDA, with the following required documentation:

- documentation that proves the Licensed Pharmacist is readily available to supervise the Pharmaceutical Establishment;
- approval from the JPA;

- a copy of the Licensed Pharmacist's registration with the JPA;
- a copy of the national identification for the Licensed Pharmacist;
- a land deed or lease agreement for the property to be used for the Pharmaceutical Establishment;
- initial approval of the Greater Amman Municipality, or any other relevant Municipality for the registration of the Pharmaceutical Entity on the said property;
- a certificate for the trade name of the Pharmaceutical Entity in the name of the Licensed Pharmacist; and
- an undertaking to abide by all issued regulations and instructions relating to the technical, health, equipment, and any other relevant specifications that the Pharmaceutical Establishment must have.

Once the application and required documentation have been submitted, a committee shall conduct an examination of the property wherein the Pharmaceutical Establishment shall be located to ensure all regulations and instructions relating to the same are met. The MOH shall obtain the following licensing fees for Pharmaceutical Establishments:

- JOD 2,000 (approximately US$4,000) for private pharmacies;
- JOD 1,000 (approximately US$1,400) for a pharmaceutical warehouse;
- JOD 1,500 (approximately US$2,000) for a pharmaceutical research and development company; and
- JOD 1,500 (approximately US$2,000) for a pharmaceutical laboratory.

Pharmaceutical manufacturers licensing

Pharmaceutical manufacturers are treated differently and have a separate licensing regime to the remaining Pharmaceutical Establishments. The application for registering a pharmaceutical manufacturer must be submitted to the JFDA with the following required documentation;

- a land deed or lease agreement for the property to be used for the pharmaceutical manufacturer
- a regulatory site plan of the property
- the company's certificate of incorporation; and
- initial approval of the Greater Amman Municipality, or any other relevant Municipality for the registration of the pharmaceutical manufacturer on the said property;

The JFDA shall review the application to ensure all requirements have been met and then conduct an examination of the property wherein the pharmaceutical manufacturer shall be located to ensure all regulations and instructions are satisfied. The committee shall then submit the documentation and the report of the examination to the Director of the JFDA within 14 working days. The Director of the JFDA then submits the documentation and a recommendation to the Minister of Health to provide the final decision within 30 working days from the date of examination.

It is worth noting that the approval to establish a pharmaceutical manufacturer shall be deemed nullified if the said pharmaceutical manufacturer has not been established within three years of obtaining the approval. The MOH shall obtain the following licensing fees for pharmaceutical manufacturer:

- JOD 500 (approximately US$700) upon submitting the application for establishing a pharmaceutical manufacturer;
- JOD 4,000 (approximately US$6,000) upon granting the licence; and
- JOD 1,000 (approximately US$1,500) upon licensing any additions to the factory.

Pharmaceutical Establishment termination

The licence for a Pharmaceutical Establishment may be terminated by a decision by the Minister of Health in the following cases (amongst others):

- if the Pharmaceutical Establishment does not commence commercial activities within one year of obtaining the licence, except pharmaceutical manufacturers who have three years as mentioned above;
- if the Pharmaceutical Establishment closes for a continued period of six months without just cause;
- if the Pharmaceutical Establishment does not abide by the relevant instructions and regulations; and/or
- if the licence has been granted based on fraudulent documentation or incorrect information.

The Pharmacy and Pharmaceuticals Law also stipulates several penalties and fines, in addition to the termination of the licence.

Conclusion

In conclusion, Pharmaceutical Establishments, including Pharmaceutical Manufacturers, are heavily regulated in order to advance the industry and improve the production, storage, and retail of pharmaceutical products in Jordan. Additionally, notwithstanding the regulations relating to licensing Pharmaceutical Establishments, the JFDA enforces international standards in relation to the raw materials used in pharmaceuticals and the overall quality of the same in order to compete on a global scale, and in order to ensure Pharmaceutical Establishments abide by the said regulations, the JFDA has the authority to conduct scheduled inspections and issue penalties accordingly in the case of breaches.

For further information, please contact healthcare@tamimi.com.