Oman’s new executive regulations to the pharmacy laws

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Overview

The Ministry of Health of Oman (‘Ministry’) recently passed Ministerial Resolution number 113 of 2020, issuing the executive regulations of the law regulating the practice of the pharmacy profession and pharmaceutical establishments (‘Regulations’). The Regulations are a progressive step forward and codify the registration and licensing regime of medicinal drugs and pharmaceutical businesses in Oman, in addition to clarifying the process of establishing pharmaceutical research centres and pharmaceutical consultancies. The Regulations expressly repeal the Ministry of Health resolution numbers 73 of 2000, 74 of 2000, 84 of 2000, 86 of 2000 and 2 of 2001.

Registration of medicinal drugs

The Regulations clarify that, before any medicinal drug can be distributed to the public in Oman, the drug must first be registered with the Ministry. This registration requirement applies whether the drug has been locally manufactured or imported. Registration entails a process that involves providing documentation that confirms that the drug has been registered and is marketed in the country of origin and with the same chemical composition. Whether a drug is subsequently approved for registration depends ultimately on both its ‘therapeutic’ significance and the standards laid down by the Ministry. Upon registration, the Regulations stipulate that the Ministry will list the drugs that have been submitted for registration on its website, which coincides with the practice currently followed by the Ministry. Registration is valid for five years and can be renewed for subsequent periods. No changes may be made to the price, chemical composition, specifications, or manufacturing method of the registered drug without prior consent from the Ministry.

It is important to note that the Regulations expressly stipulate that the Ministry will collect samples of registered drugs at regular intervals to verify that they continue to comply with technical specifications that were submitted at the time of registration. The Ministry will step in to suspend and recall a registered medicinal drug in the following circumstances:

1. the drug is proven to be harmful or toxic or has shown to give rise to serious side effects;
2. registration of the drug in the country of origin has been revoked or production has been prohibited or limited in the country of origin;
3. changes have been made to the components of the medicinal drug, specifications, manufacturing, or marketing methods without receiving prior approval from the Ministry; or
4. the medicinal drug no longer fulfils any of the conditions that applied at the time of registration.

Pharmaceutical companies

Foreign companies that develop and manufacture medicinal drugs or herbal medicines are permitted to register those drugs in Oman. Registration enables their medicinal drugs or herbal medicines to be distributed into the Omani market by a locally appointed distributor. The key requirements (not an

exhaustive list) for a pharmaceutical company to register with the Ministry are as follows:

1. the pharmaceutical company must hold licences to operate one or more factories and be able to show that it is registered in at least three countries (which such registration the Ministry may possibly interpret as a licence to distribute those drugs in three different countries);
2. it holds a certificate of good manufacturing practice from its country of origin;
3. medicinal drugs manufactured by the company are distributed in its country of origin with the same specifications, composition, manufacturing, and analysis methods as are proposed to be distributed in Oman. The company will be asked to provide a written undertaking to the Ministry to confirm this position;
4. details of the organisation of the company must be provided including divisions, number of employees, and educational qualifications within the production, quality control, and R&D departments;
5. certificates confirming innovative discoveries during the previous ten years; and
6. details of the pharmaceutical company's distributor or representative in Oman

Once approval has been given to a pharmaceutical company to register its medicinal drugs for distribution, a licence is issued for five years, renewable. It is pertinent to note that once registered, if the pharmaceutical company undergoes a sale or merger, or acquires another pharmaceutical company, written notice must be provided to the Ministry within 90 days following closing of the applicable transaction.

Herbal medicine companies

Companies that manufacture herbal medicines, which are broadly defined under the Regulations as substances of plant origin that are used for disease prevention or treatment, may register with the Ministry provided that they are able to fulfil a number of conditions, as stipulated in the Regulations. Those conditions are the same as those for registration of mainstream pharmaceutical companies, with the addition of the following specific conditions:

1. the company has a certificate of good agricultural practice issued by authorities in that company's country of origin;
2. detailed information on the raw materials used in the composition of the medicine;
3. written evidence from the health authorities in the country of origin stating that the medicines are free from steroids, sex hormones, aflatoxin, pesticides and pest, rodent, or animal debris; and
4. written evidence from health authorities in the country of origin confirming that the medicines are free

Pharmacies

The Regulations now clarify the process required to licence a pharmaceutical establishment. The Regulations indicate that the process of documentary registration is a straightforward procedure with detailed provisions focusing on the health and safety of the premises, materials used to construct the pharmacy, and controlling the temperature of medicines. It should be noted that pharmacies are classified as either 'public', namely those that are open to the public at large, or 'private', which are enterprises that hold a licence to service the patients of private hospitals. Various conditions stipulated in the Regulations must be fulfilled before a public pharmacy is issued a licence, including assessing the maximum distance from the nearest health facility and minimum distance from other public pharmacies in that vicinity. Private pharmacies are subject to fewer conditions given that they are generally in existence for the purpose of serving the patients of private hospitals. The key condition for private pharmacies is that they must be located within a private hospital and have a total internal area of no less than twenty square metres.

Pharmaceutical warehouses

The Regulations now expressly regulate the licensing of warehouses that have been established to sell medicinal drugs to government health institutions in Oman, other pharmaceutical warehouses, and other

entities approved by the Ministry. These warehouses are not permitted to sell medicinal drugs to the public or to offer samples. The structure, size and internal conditions of the pharmaceutical warehouse are all strictly controlled under the Regulations, but are likely to be fairly easily satisfied by most commercial premises in Oman. Before a licence can be issued to operate from the warehouse, the owner of the warehouse must adduce evidence that it has entered into an arrangement under which a specialist service provider will remove and dispose of all damaged and expired medicinal drugs

Scientific offices

Scientific offices are classified as establishments that contribute to scientific studies and research in co-operation with scientific centres in Oman. Such offices serve other purposes, such as raising health awareness, contributing to vocational learning programmes, and supporting various scientific activities. Obtaining a licence to establish a scientific office requires a full-time pharmacist who will act as manager of the office, but who is not permitted to sell medicinal drugs or offer free samples to the public. Before a licence can be issued, it must be shown that the scientific office is not part of any other pharmaceutical establishment.

Pharmaceutical consulting firms and pharmaceutical research centres

Pharmaceutical firms, particularly those based outside Oman, may have a desire to provide consultation, research, or studies in connection with pharmacy practice and improve awareness through the organisation of scientific events. In such circumstances, a licence to operate a consulting firm is required. Licensing requirements are minimal but it is important to be aware that the manager of the firm must be a full-time pharmacist of Omani nationality. The Regulations outline the purpose of pharmaceutical research centres of carrying out clinical research and medical analysis on volunteers for the purpose of ascertaining the stability of medicinal drugs. A pharmaceutical research centre is capable of being established and licensed in Oman provided it meets certain criteria, the key on being that the centre must satisfy global clinical GMP and laboratory GMP standards.

Medical supply companies

A separate and distinct classification under the Regulations relates to companies that wish to import medical devices into Oman. Those companies are subject to a controlled registration process that involves providing evidence of quality management and regular technical inspections in the country of origin. Although registration of the medical device is usually a condition of importation into Oman, the Regulations grant the Ministry the power to approve the importation of unregistered medical supplies in exceptional situations and subject to rules that are due to be published in the future. Products that are found to be unsafe or that have been altered after the registration process has been completed and without the Ministry’s consent will have their registration revoked. In all cases, advertising of and promotional literature for registered medical supplies may not be distributed in Oman without the prior approval of the Ministry.

Conclusion

The Regulations are a helpful, single point description of the licensing regime for the various entities that are capable of registration under Omani healthcare law. In circumstances where a foreign pharmaceutical business may be looking to ascertain the viability of formally establishing itself in Oman, it will be able to make use of the various entities available under the Regulations all of which are considered different components within the mainstream pharmaceutical sector. Registration to distribute medicinal drugs or medical devices can be undertaken by utilising the services of a local distributor or authorised representative. In other circumstances, registration and licensing with the Ministry of Commerce, Industry and Investment Promotion (previously, the Ministry of Commerce and Industry) will be a prerequisite to the

registration of a pharmacy, pharmaceutical warehouse, scientific office, or pharmaceutical consulting firm with the Ministry of Health.

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