

## **Requirements for Establishing a Pharmaceutical Manufacturing Plant in Kenya**

Author's Name

Institution name

## **Requirements for Establishing a Pharmaceutical Manufacturing Plant in Kenya**

The Kenyan pharmaceutical industry is ever booming due to the significant technological and scientific developments and the increasing opportunities for importers, exporters, distributors, and manufacturers. In conjunction with other laws, the Kenyan Pharmacy and Poisons Board (PPB) controls the trading operations in healthcare technologies and products. In particular, the Pharmacy and Poisons Act, CAP 244 of the Laws of Kenya, provides for the control of pharmaceutical trade and professionalism within the republic (Siyoi et al., 2006). The procedures, laws, and regulations for establishing a pharmaceutical industry in Kenya include the following.

### **Persons and organizations Permissible to Operate a Pharmaceutical Company**

1. Fully registered and licensed pharmaceutical technologists or pharmacists can own a pharmaceutical enterprise.
2. Fully qualified medical practitioners, veterinary surgeons, or dentists with sufficient proof before the PPB that they urgently require a specific pharmaceutical product not available in the country.
3. Representative of the people or businesses involved in selling or supplying drugs subject to the issuance of a working permit from the PPB.
4. Partners businesses or individuals for which the superintendent pharmaceutical facility should have the most shares with proof of the same in the affidavit in the application.
5. Companies involved in the manufacturing or distribution of pharmaceutical products.

### **Premises Registrable for Conducting Pharmaceutical Businesses in Kenya**

1. Premises for manufacturing pharmaceutical products.
2. Premises for conducting the businesses of pharmacists or pharmaceutical technologists.

3. Premises for running businesses as a pharmacy on either retail or wholesale.

#### **Procedure and Requirements to Start the Pharmaceutical Company**

1. The person must have a duly registered business, which can be a limited company, partnership, or sole proprietorship.
2. The person makes an application in writing to register the facility, followed by filling the set forms and submitting the academic qualifications of the pharmacist, including a copy of the pharmaceutical degree/diploma certificate or enrollment certificated to the Board. The applicant pays KES 2,500 for the annual practice license and KES 5,000 for premise registration. The whole pharmacy application should also be accompanied by another KES 5,000 to cater for the wholesale dealer's license fee.
3. The premise should have the appropriate floor plan, including the facility's recommended reference textbooks and equipment.
4. The PPB then reviews the application documents, and the Board's practice committee may organize a physical interview or meeting with the applicant.
5. The PPB then sends a pharmaceutical inspection officer to determine the eligibility of the applied business while inspecting the suggested premise.
6. Following the completion of the evaluation process, PPB gives the annual registration certificate of the premise or advises the applicant in writing if the application is unsuccessful, providing the associated reasons. The applicant can then revise and comply with the applicable provisions and then reapply, upon which the Board shall issue the license if satisfied.

The above regulations by the Government of Kenya through the PPB promote good practices in the pharmaceutical business on manufacturing, distribution, and safe management of

process wastes. The industry is a much more profitable venture in the country and the region with minimal competition and a provisional guarantee for success. Most of the applications to an industry in this sector that comply with the provisions have been successful.

## Reference

Siyoi, F., Mohamed, I., Ochieng, W., & Mbwiri, P. (2006). *Guidelines for Registration of Premises and issuance of Wholesale Dealer's License* [E-book] (1st ed., pp. 1 - 16). PHARMACY AND POISONS BOARD. Retrieved 30 September 2022, from [https://infotradekenya.go.ke/media/premises\\_guidelines%20\(2\).pdf](https://infotradekenya.go.ke/media/premises_guidelines%20(2).pdf).