الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

The Registration Rules of Pharmaceutical, Herbal and Health Product Manufacturers and their Products

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Only the Arabic version of this Regulation is authentic and it is applicable when there are differences with this translation

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Saudi Food & Drug Authority
Drug Sector

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Saudi Food & Drug Authority

Vision and Mission

Vision

To be a leading international science-based regulator to protect and promote public health

Mission

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed

Document History

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2.0	Drug Sector	25 August 2022	English translation
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Table of Contents

INTRODUCTION

At its meeting No. (1150) dated 9 / 11 /1444 AH, the Registration Committee of Manufacturers of Pharmaceuticals and their Products has approved the updated the Registration rules of Pharmaceutical, Herbal and Health Product Manufacturers and their Products, based on Article (20/4) of the Implementing Regulations of the Law of Pharmaceutical and Herbal Establishments and Products, which stated that the registration committees must conduct the update tasks for the Registration rules of Pharmaceutical and Herbal Products.

These rules aim to set the regulatory frameworks for registering Pharmaceutical, Herbal and Health Product Manufacturers and their products.

Chapter 1

Definitions

Article (1)

Taking into consideration the definitions mentioned in the Implementing Regulations of the Law of Pharmaceutical and Herbal Establishments and Products, the following terms and phrases, wherever mentioned herein, must have the meanings ascribed thereto unless the context requires otherwise:

- **SFDA**

  Saudi Food & Drug Authority.

- **Committee**

  The Registration Committee of Manufacturers of Pharmaceuticals and their Products.

  The Registration Committee of Manufacturers of Herbal and Health and their Products.

- **Pharmaceutical Product**

  A pharmaceutically manufactured product containing one substance or more, and used externally or internally in treatment or prevention of human from diseases.

- **Innovative Product**

  A product that includes new chemical entity and introduced by the innovator company (or the partner).

- **Biological Product**

  Biological products that are derived from biological sources or produced by using biotechnology methods such as vaccines, blood derivatives, recombinant proteins and gene/cell therapies.

- **Generic Product**

  A product created to be equivalent to the innovative / brand name product in dosage form, strength, route of administration, quality, performance characteristics and therapeutic indication(s).

- **Herbal Product**

  Any plant or herb that have medical claims and manufactured in a pharmaceutical form.

- **Health Product**

  Any product manufacture in a pharmaceutical form that contains a low-risk chemical substance or more used to maintain or improve health through pharmacological, immunological or metabolic effect.

- **Dosage Form**

  Physical manifestation of a product that contains the active ingredient(s) and inactive ingredient(s) that are intended to be delivered to the patient in individual doses.

- **Company**

  The owner of one or more manufacturer or has the right to manufacture or market a product and licensed to operate in accordance with the established regulations.

- **Manufacturer**

  The facility where the pharmaceutical, herbal, health products and active pharmaceutical ingredients are manufactured.

- **Growing Local Manufacturer**

  A manufacturer with an industrial license from the related authorities in the kingdom, after three years from the date of registering the first product, it will not be considered as a Growing Manufacturer.

- **Country of Origin**

  The country of the manufacturing company or marketing authorization holder, where the regulatory authority issues the Certificate of Pharmaceutical Product (CPP) or Free Sale Certificate.

- **Marketing authorization Right Holder**

  The company that has the right to market the product in the Kingdom and has full responsibility for its quality, efficacy, safety and post-marketing follow up in addition to the related procedures, i.e. sale, recall or termination.

- **Contract Manufacturing**

  The instance where a company with manufacturing rights or marketing a product by contract with another company for the purpose of partial or full manufacturing.

- **Complete Manufacturing of Pharmaceutical Products**
  - **Chemical and Herbal Products:**

    All manufacturing process of the finished product, starting from the processing of active (raw) ingredients until the packaging stage.
  - **Biological Products:**

    Any step in the main manufacturing process producing an active ingredient or finish product. Typically, these processes start by using substances that are derived from a biological source or genetically modified cells by biotechnology through the production stages by means of incubation and purification processes. Accordingly, the manufacturing of the finished product, which often includes the addition of excipients, sterile filtration and filling, with the exception of primary and secondary packaging.

- **Conditional Approval**

  An approval issued for products that are determined by the SFDA when technical requirements that must be provided in the dossier are not met or completed and the benefits of the product outweighs its potential risks.

- **Tentative Approval**

  An approval for the consideration of a products registration associated with a certain time frame determined by the SFDA until the registration of the product.

Chapter 2

The Registration of Pharmaceutical, Herbal and Health Product Manufacturers

Article (2)

The foreign companies that do not own a commercial investment license from the Ministry of Investment must appoint an agent or more for each pharmaceutical or herbal product that is intended to be marketed in the kingdom. Also, a local company can make a contract with a warehouse or more for marketing pharmaceutical and herbal products.

Article (3)

The companies (or the accredited agents) interested in manufacturer registration submit the following data and documents:

1. A certificate issued by the regulatory authorities in the country of origin confirming its compliance with good manufacturing practices (GMP) or the equivalent requirement related to the herbal and health products, including proof of periodic inspections by the mentioned authorities.
2. A list of the manufactured products, whether owned by the company or for its account or by contract manufacturing or for other companies and the dates of their registration and marketing in the country of origin and countries where such products are marketed.
3. A list signed by the company including names of the countries where such products are registered accompanied with a copy of the registration certificates.
4. Provide the site master file.
5. The production lines that the company wants to register.
6. Paying the inspection fees.
7. Signing the acknowledgment of publishing the Committee's decisions.

Article (4)

The application for renewal of a manufacturer's registration license is submitted at least six months before its expiration accompanied by the following documents:

1. A certificate issued by the regulatory authorities in the country of origin proving its compliance with good manufacturing practices (GMP) or the equivalent requirements for herbal and health products, including proof of periodic inspections by the mentioned authorities.
2. A list of products marketed in the Kingdom that are manufactured by the manufacturer whether it is owned by the company or for their account or by contract manufacturing or owned by other companies.
3. Provide the site master file.
4. Paying the inspection fees.

Article (5)

The SFDA inspects the manufacturer to ensure the implementation of Good Manufacturing Practice (GMP).

Article (6)

It is allowed for growing local manufacturers to contract with other manufacturers to manufacture their products, whereas the growing local manufacturer is the marketing authorization holder of these products while committing to obtain a certificate for Good Manufacturing Practice (GMP) Certificate within three years from the date of registration of the first product at the SFDA.

Article (7)

The Pharmaceutical and herbal product companies are allowed to apply for registration of additional production lines other than what was provided in the Saudi Drug Registration (SDR) system in accordance with the following conditions:

1. The company determines the additional product when contacting the SFDA.
2. The letter must include a commitment to register the additional product within a period of no more than two years from the date of visit.

3. If the company failed to register the additional product, the justifications must be submitted to the SFDA.

Article (8)

The marketing authorization holder of a product must notify the SFDA of any sale, waiver or transfer of the manufacturer's ownership or any other action related to the company or one of the registered manufacturers within ninety days from the completion date of the transaction.

Article (9)

In case of any changes to the manufacturer's facility, or the production lines or a relocation of the facility, the manufacturer must commit to the articles stipulated in the Implementing Regulations of the Law of Pharmaceutical and Herbal Establishments and Products as well as the SFDA Guidelines for Variation Requirements. In addition, SFDA may assign a technical team to inspect manufacturer to ensure the implementation of Good Manufacturing Practice (GMP) after paying the inspection fees.

Chapter 3

The Registration of Pharmaceutical, Herbal and Health Products

Article (10)

The imported product submitted for registration must be registered and marketed in the country of origin before its registration in the kingdom. The justifications must be stated if the imported product is not registered and marketed in the country of origin. In addition, a CPP or free sale certificate (FSC) of the product with the same Formula issued from one of the Stringent Regulatory Authorities (SRA) must be submitted (according to the Regulatory Framework for Drugs Approval). Moreover, SFDA may make an exception from this Article in cases of critical and necessary drugs that SFDA deems necessary in the market.

Article (11)

SFDA has the right to implement the principle of reliance on the scientific assessment performed by other regulatory authorities in the following cases:

- Reliance on scientific assessment outcomes of Stringent Regulatory Authorities (SRA) for regulatory decision-making in registration in accordance with the Regulatory Framework for Drugs Approval.
- Reliance on decisions of regulatory authorities regarding the post-marketing surveillance of safety, efficacy, and quality of pharmaceutical products.

Taking into consideration that the regulatory decision made by reference regulatory authorities does not necessarily mean that SFDA will undertake the same.

Article (12)

The registered local manufacturers must inform the SFDA before the start of full or partial manufacturing of a product that is not registered or the filling process, packaging process either primary or secondary, or manufacturing of active pharmaceutical ingredients for other (local or foreign) pharmaceutical companies if the product is only for the export purposes. SFDA issue a CPP or FSC, Taking into account that this certificate must not be considered a registration of the product, according to the following requirements:

1. A letter from the company stating the start of manufacturing for the purpose of export indicating the following:
    - Trade and generic names.
    - Concentration and pharmaceutical form.
    - Pack size.
    - Manufacturing steps.
    - Exporting countries.
2. A commitment not to market the product in the Kingdom before registration.

Article (13)

SFDA must register the products in accordance with the Pharmaceutical and health products establishments Law and its Implementing Regulations, subject to the following requirements:

First: the application for registration of the product must be submitted accompanied with a complete file of documents as defined in the guidelines that published on SFDA website.

Second: If the pharmaceutical product submitted for registration is manufactured by the contract manufacturing, one of the following conditions in addition to what mentioned in "First" of this Article must be met:

- The companies that carrying out the contract manufacturing must be in the same country of the marketing authorization holder.
- The product must be difficult to be locally manufactured (manufacturer using technologies that are not locally available) and SFDA deems it necessary to be provided in the Kingdom.
- The product is innovative or a critical / necessary generic product that SFDA deems it necessary to be provided in the Kingdom.
- One of the companies carrying out the contract manufacturing must be a local company.

Third: In case a company that holds the marketing authorization of innovative pharmaceutical product authorized another pharmaceutical company (Under License) to manufacture such product, fully or partially, and market it with the same trade name and specifications for the parent company, the company must meet the following conditions:

1. The manufacturing company must be a local company, and the foreign pharmaceutical companies allowed to register products which manufactured under license of innovating companies according to the following conditions:

- Their manufacturing or marketing must not be limited to the Saudi market.
- It is difficult to be locally manufactured.

2. A written approval must be obtained from the licensing company to allow the local or foreign company to manufacture and market its product in the Kingdom.
3. In case the innovative product is registered, its registration must be suspended after the approval of registering product of the licensed company, while it is necessary to ensure continuity of product's availability in the local market throughout the transition period.
4. In case of the expiry of licensing agreement, the Suspension of registration of the licensing company's innovative product is ceased, and registration of product for the licensed company will be cancelled, while it is necessary to ensure continuity of product's availability in the local market throughout the transition period.
5. The local companies exempted from bioequivalence studies for the products that are manufactured under license from other companies, as following:
   - The active ingredients, their sources, excipients involving in the composition of product, method of manufacturing, pharmaceutical form, concentration, package and all product's specifications must completely comply with such specifications of the product manufactured by the licensing company.
   - The product must not be modified-release pharmaceutical form.
   - Submitting comparative dissolution study.
6. The licensing company must conduct all required regulatory analyses to the product manufactured under license of the local or foreign company to ensure its conformity with the manufacturing specifications approved by the licensing company. This must be conducted to the first batch produced by the local or foreign company of the product manufactured under license of the licensing company. The results of shall be sent to SFDA accompanied with results of analysis of such batches conducted by the local or foreign company.

Fourth: The local company that manufactures the innovative product, partially or fully, may enter into an agreement with the licensing company to manufacture a second brand with a trade name owned by the local company. However, the innovative product must obtain a valid patency and the product must be similar in all technical specifications with the parent company's innovative product:

1. The second brand is exempted from bioequivalence studies according to the following:

- The active ingredients, their sources, excipients contained in the product formula, manufacturing process, pharmaceutical form, concentration, package and all product's specifications must be completely identical with such specifications of the product manufactured by the licensing company.
- The product must not be a modified-release pharmaceutical form.
- Submitting comparative dissolution study.

2. The Marketing Authorization Holder of the second brand must submit an application for relocation of the product manufacturing site after expiry of the agreement in case manufacturing is completely transferred.

Fifth: it is not allowed to register a pharmaceutical product for pharmaceutical company that holds a marketing authorization for a specified product and does not have a pharmaceutical manufacturer. In addition, SFDA may exclude locally manufactured or the innovative or generic products that SFDA deems necessary to be provided in the Kingdom.

Sixth: The product that is submitted for registration may only have two sources of manufacturing as a maximum. In addition, the company may add more than one manufacturing source for its registered product along with a commitment to follow the SFDA Guidelines for Variation Requirements.

Seventh: The company may enter into an agreement with a local manufacturer having a registered generic product to manufacture the same product with a different trade name, considering that it is a third generic product or above. The emerging local manufacturer must be exempt from this condition.

Eighth: It is not allowed to register two products with the same active ingredient with different trade names owned by one marketing company unless they hold different therapeutic claims or different concentrations.

Ninth: The product’s file submitted for registration can not be modified after starting of the scientific evaluation stage. In addition, SFDA may accept the necessary modifications at the business validation stage.

Article (14)

The Committee determines the legal and distribution status of pharmaceutical products undergoing registration according to the following:

1. Prescription only medicine
2. Controlled prescription medicine
3. Pharmacist only medicine.
4. Over the counter (OTC) medicine.

The products' place of distribution must be determined according to the following:

1. Pharmacies.
2. Hospitals.
3. Products for sale in food retail store that meet storage conditions.

Article (15)

The Marketing Authoraztion Holder of any pharmaceutical product in the Kingdom must follow the pharmacovigilance requirements provided for in the Guideline on Good Pharmacovigilance Practices published on SFDA website.

Article (16)

The companies must provide Patient Information Leaflet (PIL) in Arabic and English languages and summary of product characteristics (SPC) in English for the pharmaceutical product and uploaded to the Saudi Drug Information (SDI) platform. In addition, the leaflet may not be included in the product's package in case its distribution is limited to the hospitals according to the CPP.

Article (17)

When performing any variation to the registered product, the company must inform SFDA by submitting an application for such change according to SFDA Guidelines for Variation Requirements.

Article (18)

SFDA grants the conditional approval of registration of pharmaceutical products, as SFDA deems appropriate, that pass the scientific evaluation according to the following procedures:

- The product will be submitted to the Committee for issuance of conditional approval.

- When the company meets the requirements, the final approval must be issued and the product is priced after being submitted to the Committee.

Article (19)

SFDA issue a letter of tentative approval for product registration until the legal and technical requirements are met. In addition, the Committee may decide on the registration of product upon expiry of the time limit that SFDA determines based on the available legal grounds.

Article (20)

SFDA rejects the new registration applications, renewal and variation applications if the manufacturer is suspended unless an application for objection is submitted within the legal time limit. In addition, the company must submit a new application after the suspension is ceased.

Article (21)

The pharmaceutical or herbal product is considered locally manufactured if it is completely manufactured in the Kingdom.

Article (22)

The companies must follow the guidelines and circulars published on SFDA website and therein contained conditions and requirements.

Article (23)

SFDA, after coordination with the company, publish scientific evaluation reports on SFDA website after completion of legal procedures for registration of pharmaceutical or herbal products.

Article (24)

SFDA periodically analyses random samples of locally marketed products to verify compliance with technical regulations. SFDA reserves the right to publish the results of out of specification batches after coordinating with the company.