The activity of manufacturing medical products for others

A- Conditions for registration, renewal and modification of the activity of manufacturing medical products for third parties:

1. That the project and the activity of manufacturing, production or assembly are with third parties registered in both the commercial registered and the tax card of the facility.

2. The facility must have a clear approval from the Unified Procurement Authority to extract or renew the production requirements register or an industrial register certificate.

3. The activity must be in the clear approval letter issued by the Unified Procurement Authority with a fixed period (beginning and end) of quantities and items

4. The activity must exist and evidenced in the license to practice the profession issued by the Medicines Authority.

5. The pharmaceutical manufacturing plan approved by the Unified Procurement Authority should specify the types of medicines or cosmetics - their place of manufacture - the active substances with a fixed period (beginning and end) - items and quantities.

6. The project and activity data must be identical in the commercial register, clear approval letter, operating license and tax card.

7. The person concerned, or whoever has the right to manage and sign, or the agent should not work for the government

B- Documents for registration, renewal and amendment of the activity of manufacturing medical products at others:

1. A production requirements card application form signed by the person who has the right to manage and sign in front of the competent employee or signed by the agent or authorized representative.

2. A copy of the national ID card or passport for those who have the right to manage, sign, and the original for viewing

3. If the applicant is an agent or authorized representative:

• A copy of the national ID card or passport of the agent or authorized representative and the original for review.

• A copy of a notarized authorized from the real estate registry and the original for perusal (even a second agent is accepted only) or the original authorization form signed by the competent employee who has the right to manage and sign, or certified by an approved bank.

• Acknowledgment of the validity of the authorized signed by the agent (if the applicant is an agent of the facility).

4. A recent official extract from the commercial register, valid for a period of not less than 90 days, and a recent issue of which no more than 90 days have passed, including the title of the activity - manufacturing, production or assembly activity with others - data of those who have the right to manage and sign - the name and trade name of the facility.

5. A copy of the license to practice the profession from the Medicines Authority and the original for perusal, specifying the validity period of the activity, specified (beginning and end) - quantities – items

6. A copy of the drug manufacturing plan approved by the Drug Authority, specified in it

Types of medicines or cosmetics - place of manufacture - active substances - fixed duration (beginning and end) - items and quantities.

7. A copy of the operation contract between the factory and the facility, in conformity with the pharmaceutical manufacturing plan approved by the Drug Authority, and the original for perusal.

8. A copy of the tax card is identical to the commercial registration data and the original for viewing,

- Or a basic data document for the taxpayer (if the project is new and has not been issued with a tax card).

9**. In the absence of an industrial register**:

• A letter of clear approval issued by the Unified Procurement Authority to extract or renew a record of production requirements, including a specific activity period (beginning and end) - quantities - items.

• Completion of the “undertaking of activities that do not have an industrial registry” signed by those who have the right to manage and sign in front of the competent employee or signed by the agent or authorized representative.

10. In the case of an industrial registry:

• A copy of the certificate of the industrial register valid, unconditionally or temporary, and the original to see that the activity includes - its address - duration (beginning and end) - items and quantities - commercial registration number - the name and trade name of the facility.

• Completing the "Industrial Record Undertaking" signed by the person who has the right to manage and sign in front of the competent employee or signed by the agent or authorized representative.

C- **Notes on the registration, renewal and modification of the activity of manufacturing medical products with third parties**:

1. The document indicative of the activity is the industrial register or the clear approval letter issued by the Unified Procurement Authority.

2. The document evidencing the practice of the activity is the license to practice the profession.

3. The items and quantities allowed to be imported are determined on the production requirements card according to the clear approval letter and the manufacturing plan, and more than 5 products are issued in a data certificate or a certificate of products independent of the card.

4. The address of the activity in the production requirements register card is the address recorded in the clear approval letter issued by the Unified Procurement Authority and the license to practice the profession, not the address of the main center of the commercial registry.

5. **In the case of an industrial registry**:

• It is not required to state in the industrial registry that it is permanent, but it must be unconditional or not temporary.

• Both the industrial register and the operating license are considered temporary if it is required to reconcile the situation with them (settlement of the environment file - civil defense).

• Upon renewal, if the industrial register is temporary, a temporary card can be obtained for production requirements, provided that the industrial register submitted at registration is permanent

6. In the case of submitting a commercial registry or a process contract whose validity period is less than 5 years, the expiry date of the production requirements card is the nearest of the two dates.

7. Cancellation of the operating license (operational contract) followed by the cancellation of the production requirements register card