Central Administration Pharmaceutical Products
General Administration For Biocides Registration

Notice to applicant

Notice to Clarify the Mechanism of Conversion a Product Registered as a Human Pharmaceutical Product(Gargle) to Antiseptic

Year 2023

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1. Introduction:

This notice is concerned with clarifying the procedures of converting the (gargle) product from a human pharmaceutical product to an Antiseptic product. Whereas the antiseptic product registration was approved as a pharmaceutical form (gargle) provided that no therapeutic indications for the product are written on the package, in accordance with the decision of the specialized committee for registration of household, public health pesticides and antiseptic at its session held on April 4th,2023, as well as the decision of the Technical Committee for Drug Control issued on June 4th, 2023 for the active ingredients that have antiseptic properties (such as povidone-iodine), since the mouthwash was previously registered as an antiseptic only and not as a "gargle ".

2. Scope of Implementation:

This mechanism shall be applied to human pharmaceutical products registered / or have obtained approval to proceed with the registration or re-registration procedures in the pharmaceutical form "gargle" which contain only antiseptic active ingredients and do not contain any other active ingredients, in case of the conversion is desired by the company, provided that no therapeutic indications for the product are written on the package.

3. Definitions:

Antiseptic Products: They are the products that contain active ingredients that have antiseptic properties only with no therapeutic purpose. Such products kill or stop the growth of pathogenic microorganisms, whether they are bacteria, viruses, fungi or yeasts. They are used only for the purpose of reducing or prevention the onset of a disease and they have not any other therapeutic purpose or medical effect.

4. Procedures:

How to Apply:

The company desirous to convert the product from a human pharmaceutical product to an antiseptic product shall carry out the following:

- The company shall submit an official request approved by the Chairman of the Company's Board of Directors to the General Administration of Human products Registration to state whether or not the product is registered as an antiseptic. In case of the product is subject to registration as an antiseptic, the administration of Regulatory Affairs of Human Products shall issue a letter addressed to the company with the status of the product after paying the service fee.
- The company shall upload the application file for conversion from a human product to an antiseptic through the link designated for antiseptics/disinfectants at the General Administration for the Registration of Biocides on Saturdays and Tuesdays of every week from 9 a.m. to 3 p.m.

Link to upload the antiseptics/disinfectants files:
https://forms.gle/AVNognhG9PfTXK976

Documents required in the (requested conversion file) submitted on the antiseptics/disinfectants link:

1. A (valid) Registration license of the human product or evidence of preliminary approval for registration/re-registration procedures as a human medicine.
2. A statement by the General Administration of Human Products Registration on the product status.
3. Payment receipt for the service of the requested conversion (re-writing the license).
4. The new package (leaflet and label) not including any medical indications of the product.
5. A payment receipt of the service fee for reviewing the package and leaflet.
6. A scientific reference for the product.
   - **The file submitted by the company shall be reviewed then an e-mail shall be sent to the company**
   - **In case of not fulfilling any of the required documents the file shall be rejected and the company shall re-upload the file.**

For the registered product that has a registration license as a human medicine:

- The product shall be presented to the specialized committee for registration of household, public health pesticides and antiseptics to give the product a new registration number as an antiseptic and to issue a registration license for the product as an antiseptic with the remaining period stated in the registration license of the product as a medicine.
- An e-mail shall be sent to the General Administration of Human Products Registration to cancel the product registration as a human medicine in accordance with the applied procedures of cancelling.

For the product under registration / re-registration as a human medicine:

- In the case of products that have obtained preliminary approval for registration/re-registration procedures as a human medicine, the product registration file shall be entirely uploaded in accordance with the check list for the registration of antiseptics/Disinfectants accompanied by the statement issued by the General Administration of Human Products Registration of the product status.
- The company is allowed to submit a petition to consider the conducted studies to be reviewed and presented to the specialized committee for registration of household, public health pesticides and antiseptics. An approval is issued for the product as an antiseptic, containing a condition of carrying out the required studies.
- An e-mail shall be sent to the General Administration of Human Products Registration to cancel the product as a human medicine in accordance with the applied procedures of cancellation.