Ministry of Health
in
Suriname

Management and Central Administration

No: DVG 189/'25 **Paramaribo, February 19th, 2024**

To: importers of medicines

Subject: Instructions on submission of registration dossiers and applications for import licenses

Dear importer,

The Ministry of Health brings to your attention the following:

The Registration Committee (Registratie Commissie; hereinafter referred to as: RC) registers a medicinal product in the Register of Packaged Medicines in Suriname (hereinafter referred to as: the Register) in accordance with article 4 of the Packaged Medicines Decree (Besluit Verpakte Geneesmiddelen; G.B. 1973 no. 155; hereinafter referred to as the Decree), provided that the criteria mentioned in this article are met. In addition, in accordance with Article 3 paragraph 3 sub a of the aforementioned Decree, the RC has the authority to obtain further information, in written or verbally, from the applicant and from the government authority referred to in Article 3 paragraph 1 sub h (i.e. the government authority in the country of manufacture of the packaged medicinal product considered competent by the RC for that purpose), or the relevant authority in another country.

When importing medicines, pursuant to the Goods Movement Act (Wet Goederenverkeer; S.B. 2003 no. 58, as it reads after amendments made to it by S.B. 2004 no. 121, and the accompanying Negative List Decree (Besluit Negatieve Lijst) S.B. 2003 no. 74), an import license is required, issued by the Import, Export and Exchange Control Department (Dienst Invoer-, Uitvoer- en Deviezencontrole) of the Ministry of Economic Affairs, Entrepreneurship and Technological Innovation and approved by the Pharmaceutical Inspectorate (FI). When applying for the import license, the importer must request the RC for proof of registration in the Register of the medicines to be imported (the so-called 'registration certificate or import certificate') and submit it to the Ministry of Economic Affairs, Entrepreneurship and Technological Innovation and the FI as substantiation for the import license application.

In view of recently reported cases to the Ministry of Health, the RC may in some instances be forced to apply article 3 paragraph 3 sub a of the Decree more stringently when importing medicines and to request additional proof that the medicines to be shipped meet the specifications

mentioned in the registration dossier. This in order to optimally guarantee the quality of medicines available in Suriname.

From now on, the RC and FI use their authority to request additional information, for reviewing applications:

1. for the inclusion of packaged medicinal products in the Register and/or
2. for an import license of packaged medicinal products,

in case where the manufacturer of the products has not registered and/or marketed them in a "highly regulated"[1] country.

The additional information will in any case involve of a certificate of analysis (CoA) of the packaged medicinal products concerned, originating from an independent laboratory which is approved by the regulatory authorities of the country of preparation, and must comply with the applicable Good Laboratory Practice (GLP) guidelines (e.g. WHO prequalified, ISO 17025 accredited, OECD principles of GLP and Compliance Monitoring of OMCL (Official Medicine Control Laboratory). The CoA must show that the packaged medicinal product meets the specifications stated in the registration dossier and applies to each batch of the medicinal product for which an application for registration is made.
This requirement for additional information also applies to the import of products registered in a "highly regulated" country and where production takes place in a manufacturing facility other than the specified in the registration dossier.

For manufacturers who produce medicinal products, which are not registered and/or not for sale in a "highly regulated" country, the RC and FI may waive the obligation to submit additional quality proof, if they are packaged medicines that

- have been registered in Suriname for a long time and have already been imported and marketed in Suriname several times and:
- have been used without known quality problems.

RC and FI will in these cases make a risk assessment based on their professional expertise.

Further information on the registration procedure can be found on the following website https://gov.sr/ministeries/ministerie-van-volksgezondheid/de-registratie-commissie/

Kind regards,

Drs. Rakesh Gajadhar Sukul, MSPH
Director of the Ministry of Health

Cc: Pharmaceutical Inspection Department
Deputy Head of the Registration Office
Registration Committee

[1] Countries with strict drug regulation; in practice, countries are considered as such if they are members of the PIC/S scheme (https://picscheme.org/), products that are WHO prequalified (https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products) and products from WHO listed authorities https://www.who.int/publications/m/item/list-of-who-listed-authorities-wlas