Ministerie van Volksgezondheid
in
Suriname

Directie en Centrale Administratie:
Registratie Commissie voor Geneesmiddelen, Kernkampweg 1, Telefoon: 440481
Email: registratiecommissie@health.gov.sr

The Registration Committee

The Registration Committee (RC) is a task force of the Ministry of Health that is of added value for the pharmaceutical sector and public health care. It is an independent committee that assesses scientific publications on a medicine and comes to a balanced opinion about its efficacy versus the risks. The RC thus reviews whether medicines are safe, effective and of good quality before they are admitted to the Surinamese market. In all evaluations of medicines, the interests of the patient are paramount and an informed decision is made between the efficacy and risks of the new medicine.

1. GENERAL: TASK OF THE REGISTRATION COMMITTEE

The RC's primary task is to assess packaged medicines intended for use in Suriname with regard to the preparation, composition and application of these medicines.

Packaged medicinal products shall be registered if:
- It is reasonable to assume that they possess the appraised effect;
- they are not harmful to health when used in accordance with the instructions on or accompanying the packaging;
- They comply with the relevant legal requirements.

The RC keeps a register of packaged medicines present in Suriname.

What is packaged medicine?

Pursuant to Article 1 paragraph f of the practice of medical preparation in Suriname, packaged medicine means: any medicinal product prepared in advance which is marketed under a special name and in a special packaging:
a. Packaging delivered in its entirety to the patient;
b. Packages containing quantities greater than those usual in (a).

Medicines in Suriname can be registered under the following conditions, i.e.:

UR – Prescription only, which means that the medicine must only be dispensed by a pharmacy on prescription.

UR – Specialist prescription – This is a specialist prescription, in which the initial prescription of the medicine has been issued by a medical specialist.

UA – Only pharmacy, this means that the medicine can only be dispensed by a pharmacy.

UAD – Only pharmacy drugstore, this means that the medicine can be sold in a pharmacy or at a drugstore.

How long after submission of a request to register a medicine is the application registered or not?

According to Article 4 of the Packaged Medicinal Products Decree (G.B. 1973 No. 155), an application for registration takes an average of 180 days from the day of receipt of the applicant.

Legislation regarding the registration of a medicine in Suriname:

- Amendment of the Regulation on the practice of medicine in Suriname (G.B. 1973 no. 1);
- Packaged medicines decree (G.B. 1973 No. 155);
- Amendment of the Packaged Medicinal Products Decree (G.B. 1986 no. 56);
- Further amendment of the Packaged Medicines Decree (G.B. 2017 no. 15);
- Decree of 16 June 1981, regulating the practice of medical medicine in Suriname. (S.B. 1981 No. 78).

Partnerships

The RC is an independent committee of the Ministry of Health, which participates in various international and regional networks on drug registration, including the Pan American Network for Drug Regulatory Harmonization (PANDRH network) and the Caribbean Regulatory System (CRS).

MEMBERS OF THE REGISTRATION COMMITTEE

In accordance with the practice of Art of Preparation in Suriname (G.B. 1973 no. 1), the chairman, the deputy chairman and the other members of the RC shall be appointed and dismissed by the President of the Republic of Suriname on the recommendation of the Minister of Health.

Obligations of the members of the RC

The members and associate members of the RC are obliged to maintain the confidentiality of what they have become aware in the performance of their duties concerning the preparation, composition or application of packaged medicinal products. Members shall not be in any way linked to or have any financial interests in manufacturers, wholesalers, importers or agents of packaged medicinal products.

The members of the current RC are:

Mrs. S. Baal, MSc., Pharmacist, Chairman
Ms. Drs. S. Kort, Pharmacist and Clinical Chemist, Vice-Chairman
Mr. Drs. R. Alladin, physician, member
Mr. Dr. F. Gopie, pulmonologist, member
Mr. Dr. C. W. R. Zijlmans, pediatrician, member
Mr. R. Ramnath, LLB, representative of the Ministry of Health

Code of conduct:

The following code of conduct has been drawn up by the RC in its current composition (resolution number 0086/22 & 661/22) with the aim of improving the transparency of the RC's processing methods. This code of conduct is a description of the norms and values that the RC imposes for self-regulation, which creates uniformity and transparency of the RC's actions.
Code of conduct upload

II. SUBMITTING A REGISTRATION APPLICATION FOR A PACKAGED MEDICINAL PRODUCT

A registration application can be submitted to the Registration Office. The Registration Office is a working body of the RC and is located at Kernkampweg no. 1B. The opening hours of the Registration Office are from Monday to Thursday from 07:00 – 15:00 and on Friday from 07:00 – 14:30 and can be reached by telephone at 440481.
Email:registratiebureau.volksgezondheid@gov.sr

Application registration procedure

The interested party shall apply for inclusion of a medicine in the Register of Packaged Medicinal Products, which shall be maintained by the RC. This application consists of an application file with an application form, relevant attachments and a physical sample.
The support from the registration office includes the collection of data for verification. The result of the above survey with the addition of an advice is sent to the chairman of the RC, who, together with the other members, assesses whether an application can be registered.

Relevant documentation required are: Letter 1: Data required for submitting a registration dossier (letter to be consulted below)
Letter 2: Data required for the submission of a medicinal product recommended by the Caribbean Regulatory System (letter below)

III. HISTORY OF THE REGISTRATION OFFICE

The registration office was formerly part of the Pharmaceutical Service. In the year 1981 this office moved to the Kernkampweg 1B. The chair of the RC also previously served as acting head of the Registry Office. In November 1999, Prof. Dr. E.N. Parabirsing was chairman of the RC and also acting head of the Registration Office. The building in which both the pharmaceutical inspectorate and the registration office are housed is named after him, the Prof. Dr. E. N. Parabirsing Institute.

IV. FREQUENTLY ASKED QUESTIONS

What is the difference between the registration commission and the registration office?
The registration office carries out administrative work for the registration committee. The registration committee primarily assesses files in accordance with applicable legislation.

Is it possible to reapply for registration of an existing medicine? A medicine is only registered once.

How can I tell if a medicine is registered?
In the Registration file online, you can look up whether a medicine has been registered.

How does the registration office deal with product changes?
Requests for product changes can be submitted free of charge to the registration office. These changes will also be reviewed. Additional documentation may be required to assess the product change.

Where can I reach members of the registration committee?
Communication with the registration committee takes place through the registration office at the email address: registratiebureau.volksgezondheid@gov.sr

Stop registration request?
In case registration of a medicine needs to be discontinued for any reason, this must also be made known by a letter to the chairman of the RC.

Are over-the-counter medicines also registered?
Over-the-counter medicines are also packaged medicines and must be registered. When registering the medicine, the RC indicates the status, prescription only (specialist prescription), only drugstore, pharmacy/drugstore only and free sale.

Do bandages and veterinary medicines also need to be registered?
In Suriname it is mandatory that packaged medicines are registered. There is no legislation yet that makes it mandatory that bandages, veterinary medicines and raw materials must also be registered. To guarantee good health care, it is of paramount importance that high-quality products are used.