Ministerie van Volksgezondheid
in
Suriname

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

Letter for importers of medicinal products

Attribute:.....

Subject: Data for submitting a registration dossier

Dear pharmaceutical importer,

For a smooth process regarding the processing and assessment of registration dossiers, we ask for your cooperation to comply with the following when submitting the hard copy registration dossiers. For now, it is not possible to submit a registration file electronically.

The registration dossier, CPP (Certificate of Pharmaceutical Product) and other annexes to the registration dossier must be submitted in Dutch or English.

Fast track procedure (rapid evaluation of offered medicines by registration committee for authorization on the local market).

Products from the following countries and categories follow the fast-track procedure:

1. Netherlands
2. England
3. Germany
4. Canada
5. USA
6. Belgium
7. France
8. Switzerland
9. Norway
10. Denmark
11. Sweden
12. CRS – list to be consulted through https://www.carpha.org/What-We-Do/CRS/Caribbean-Regulatory-System/
13. WHO - list of prequalified medicines, list to be consulted through https://extranet.who.int/pqweb/content/prequalified-lists/medicines/

14. Other Stringent Regulatory Authorities (SRA) with a category B and D entry, list available trough https://cdn.who.int/media/docs/default-source/medicines/regulatory-systems/wla/rev-list-of-transitional-wlas.pdf?sfvrsn=1f6c2140_7&download=true/
15. Pharmaceutical Inspection Co-operation Scheme (PICS) member countries, list available through https://picscheme.org/en/members/

For products from this group of countries/ agencies, **the following is at least** necessary:

- Cover letter on which both the director of the importer and the consultant pharmacist sign.
- Fully completed application form.
- CPP (Certificate of Pharmaceutical Product).
- SmPC (Summary of Product Characteristics).
- Sample (package leaflet enclosed) with clear registration number country of origin.
- For products from the Netherlands, instead of a CPP, a printout (with date consulted) of the website https://www.cbg-meb.nl// can be submitted, clearly displaying the pages "about this medicine" and "marketing authorization details". In addition, a statement from wholesaler or manufacturer that the same product for which a registration dossier has been submitted in Suriname is also sold/ available on the Dutch market.
- If it concerns a PICS country (clearly displayed on the application), instead of a CPP, a GMP certificate (not older than 2 years) with a clearly stated EudraGMDP number can be submitted. In addition, a statement from the manufacturer that the product is also in use/ for sale on the market in the country where it is produced.
- If the product is on the CRS list, provide a CRS recommendation certificate with CRS product reference number issued by the Caribbean Public Health Agency (CARPHA) instead of a CPP.
- *Optionally the Common Technical Dossier (Appendices A-K) with all other information.*

For all **other** countries:

- Cover letter on which both the director of the importer and the consultant pharmacist sign.
- Fully completed application form.
- CPP (Certificate of Pharmaceutical Product).
- WHO- GMP certificate from the manufacturer
- WHO- GMP certificate from the API manufacturer (raw material)
- SmPC (Summary of Product Characteristics)
- Common Technical Dossier (Appendices A-K)

- Sample (package leaflet enclosed) with clear country of origin registration number and certificate of analysis of the sample.

Additional information:

The submitting party must have a wholesale distribution authorization and be registered with the Pharmaceutical Inspection Department of the Ministry of Health as an importer of medicinal products.

The accompanying letter with a summary table of the products offered must be signed by the director of the wholesaler and by the consultant pharmacist.

Procedure:

When offering your product for registration, a checklist is used to see whether your documentation is complete and meets the requirements. If this is not the case, the file will not be processed, and you will be asked to complete documentation before offering it again.

If documentation is complete and satisfactory, the registration application will be processed.

Your cooperation is requested to comply with the above so the process of assessing registration dossiers for safety, quality and effectiveness runs efficiently and effectively.

Trusting to have informed you sufficiently.

Sincerely,

Mrs. S. Baal, MSc

Chairman registration committee

Attachment A to K

The application must consist of the following documents:

A. Complete quantitative composition of the active ingredients.
B. Flowchart of the production process
C. Accurate description of testing prescriptions of finished pharmaceutical and substances it consists of.
D. Data under tropical conditions.
E. Description of recommended and remaining effects, indications, administration, dosage (SmPC).
F. Other information for substances or combinations with insufficiently generally known action. (bio – equivalence)
G. Trade packaging and contents.
H. Copies of labels, packaging material and accompanying pieces of writing or designs of such, all in 6-fold.
I. Description of the packaged pharmaceutical.
J. Samples of administration form of finished pharmaceutical and samples of active ingredients, everything in sufficient supply for analysis.
K. Statement made by competent government authority in the country of production that the finished pharmaceutical product has been prepared in accordance with legal regulations and can be put on the market. If also registered elsewhere, countries and registration numbers.