INSPECTION AND LICENSING

The Inspection and Licensing section is mainly responsible for the following:

1) Compliance and enforcement of the Medicines and Related Substances Control Act, 2003 (Act 13 of 2003).

2) Licensing and Registration of premises.

3) Ensuring that all manufacturers in and outside the country who apply for registration of their products in Namibia and those with registered products in Namibia follow the current Good Manufacturing Practices(cGMP) as outlined in the WHO cGMP guidelines.

Details of the various activities are outlined below:

Compliance and Enforcement

The inspectorate is concerned with compliance and enforcement as its core functions. This involves:

- Current Good Manufacturing Practices: Inspection regarding compliance with GMP according to the latest WHO guidelines of Good Manufacturing Practices.
- Good Distribution Practices: Inspection regarding compliance with GDP according to the latest WHO guidelines of Good Distribution Practices.
- Compliance verification: this involves compliance verification and investigation activities in the area of medicines as defined in the Medicines and Related Substances Control Act, 2003. This involves collection of samples from distribution outlets for examination to ensure that standards are maintained post registration.
- Enforcement of the law: This involves activities to ensure compliance with the law regarding the sale and use of medicines as provided for in the Act. The activities involve inspection of pharmacies, medical practitioners, hospitals and all health facilities
- Liaising with Customs officers: Visiting all border posts to ensure that only registered medicines are imported and that importation is done by licenced manufacturers and wholesalers/distributors
- Inspection of general retail outlets: This activity is aimed at ensuring that medicines are sold only by authorized persons and in authorized premises.

Licensing and Registration of premises

The inspectorate manages and issues licences as required in the Medicines and Related Substances Control Act 13, 2003. The Inspectorate Section is responsible for ensuring that:

- Wholesalers / distributors of medicines have import/export licences.
- All health practitioners who are not pharmacists and who intend to sell/dispense have a licence for that purpose from NMRC.
- Pharmacists who prescribe and dispense medicine schedules other than schedule 1 must have a licence for that purpose.

- All medicine manufacturers in the country are registered with NMRC
- All foreign manufacturers comply with cGMP before registration of their products with NMRC and that the level of cGMP is maintained by periodic assessment or inspection of the site as the Council may determine.

Requirements

The manufacturing of pharmaceuticals requires compliance with cGMP (current Good Manufacturing Practice). All premises where medicines are manufactured must be registered with the NMRC after payment of the prescribed fee. Import/export licences are granted to registered Manufacturers, Wholesalers and Distributors. Licenses are issued for a period of one calendar year and are renewable annually during the first month of the year.

Procedure for obtaining a License for selling/dispensing of medicines

Application shall be made to Council in the prescribed format and accompanied with the prescribed fee

The business premises shall be inspected to ensure they are suitable for the intended purpose

Change of premises

Any change of a registered premise must be approved by Council.