**MANUFACTURING AND GMP INSPECTIONS**

**Legislative Mandate:**
This process is governed by Section 31 (4); (5) b; 37A and Regulation 34 (10); 35 of the Medicines and Related Substances Control Act 13 of 2003.

**Definitions:**

* **Manufacture:** “Manufacture” means carrying out operations including the purchasing of material, processing, packaging, quality control, release, and storage of medicinal products and related substances. “Manufacturing” has a corresponding meaning.

**Objectives:**
Good Manufacturing Practice (GMP) inspections are conducted in line with current WHO GMP guidelines by inspectors as per Regulation 43.

1. **Compliance with Standards:**
Any person manufacturing medicines in Namibia must follow and comply with the standards of good manufacturing practices as contained in the World Health Organisation (WHO) guidelines. Therefore, an inspection of the facility for compliance with current Good Manufacturing Practices (cGMP) is mandatory before the issuance of a manufacturing license.
2. **Support Product Registration:**
GMP inspections support the registration of products. Routine inspections ensure that all medicines registered in Namibia, as contemplated in the Act, are manufactured according to WHO guidelines on current GMP. Additionally, the conditions mentioned in WHO guidelines must be maintained at all manufacturing premises at all times.

**Requirements for Premises Registration for Manufacturing in Namibia:**
The following verified copies (verification not older than 6 months) should be attached to the application form:

* Registration certificate of the manufacturing premises from the Pharmacy Council.
* Registration certificate of the Responsible Pharmacist from the Pharmacy Council.
* Pharmacist registration certificate from the Pharmacy Council.
* Duly filled application form, Annexure XXIX (for registration of premises) and Annexure XXVII (for the manufacturing license), as per the Medicines and Related Substances Control Act 13 of 2003.

The Namibia Medicines Regulatory Council (NMRC) conducts inspections to determine whether premises comply with WHO current Good Manufacturing Practices, both for manufacturers in Namibia and manufacturers outside Namibia (product line inspections).

* **Fee Structure:** The applicable fees vary depending on the number of manufacturing blocks and the dosage forms submitted for registration, as stipulated in the fees gazette.
* **Inspection Process:** The inspection process is generally initiated by the NMRC inspection coordinator after product dossier assessment. However, local manufacturers may apply through the Registrar’s office.
* **Documentation Required:** Manufacturers must provide the current Site Master File and a list of products marketed or submitted for registration.