Section 31(5) - MANUFACTURE, PACKAGING, AND SALE OF MEDICINES AND SCHEDULED SUBSTANCES

The Council may issue a licence, upon application by a registered pharmacist, authorising the individual to manufacture, pack, and sell medicines or scheduled substances. The licence will be subject to conditions determined by the Council.

Application Requirements:

- Completed application forms for manufacturing and premises registration (Annexure XXVII and Annexure XXIX of the Medicines and Related Substances Act)
- Registration certificate of the Responsible Pharmacist from the Pharmacy Council
- Pharmacist's registration certificate from the Pharmacy Council
- Registration certificate of the entity with the Pharmacy Council
- Registration of the premises where the activities will be conducted
- Payment of the prescribed licence fee for issuance

Licence Conditions:

- The licence or permit issued under this section may be revoked if any of the conditions are not met.

Importation Conditions:

1. Compliance with WHO guidelines on good distribution practices
2. Importation of only registered or authorised medicines
3. Licence renewal applications must be submitted three (3) months prior to expiry

Exportation Conditions:

1. Only registered products may be exported
2. A quarterly report of exported products must be submitted to the Council
3. Failure to submit reports may result in the non-renewal of the licence
4. Licence renewal applications must be submitted three (3) months prior to expiry