Drug Regulatory Unit Botswana

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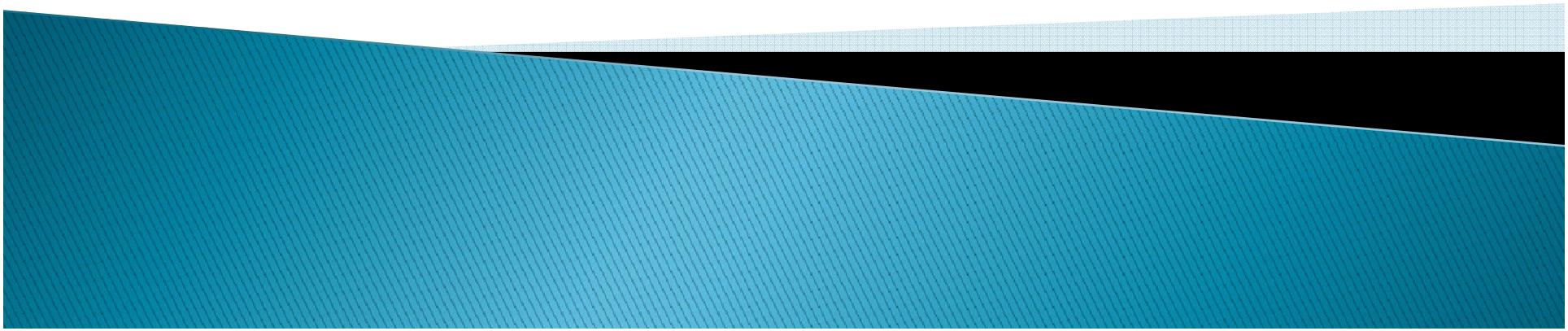
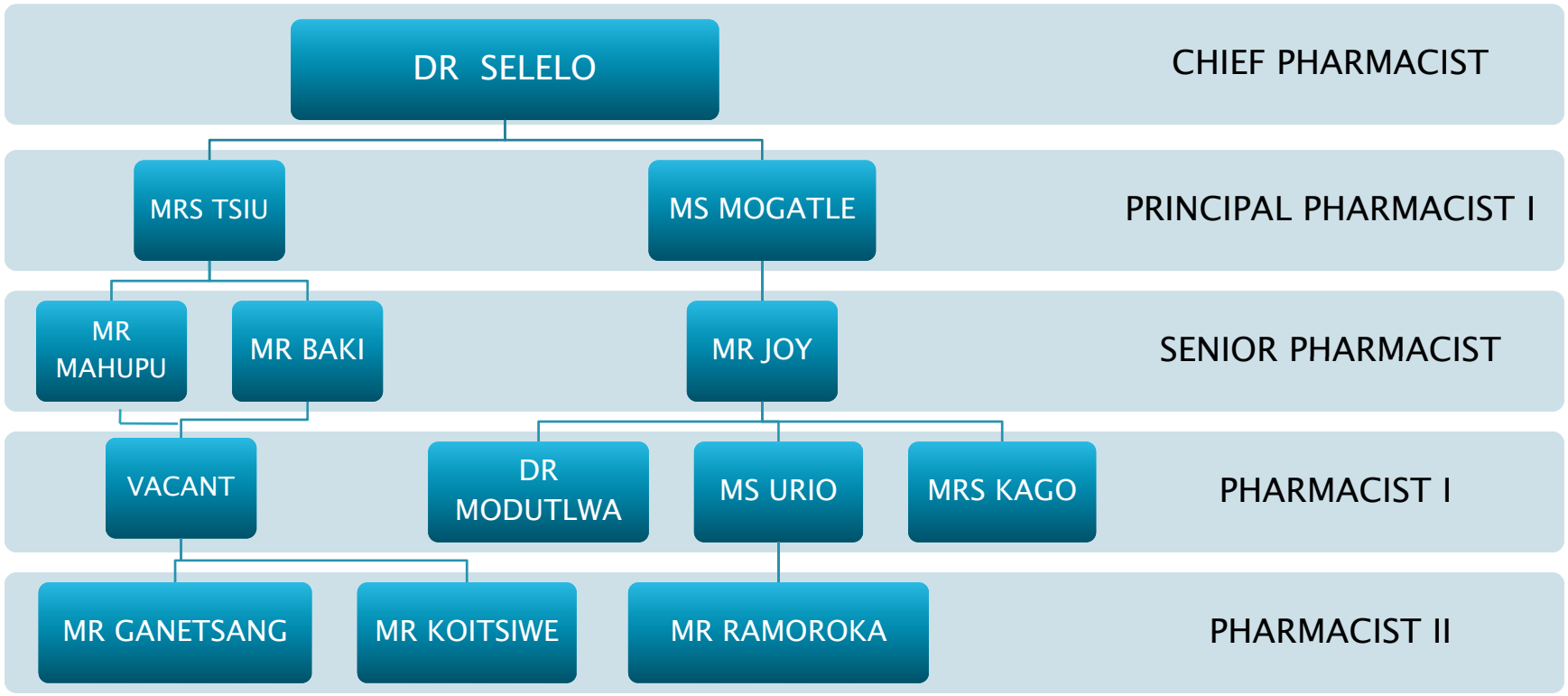
Pharmacist
Registration Section



DRU Mandate

- The DRU is the unit of the Ministry of Health responsible for ensuring that medicines used in the country are safe, effective and of good quality.
- To this end the unit is involved in the evaluation of all medicinal applications for registration, inspection of facilities where medicines are stored and distributed.
- The mandate extends to ensuring that once the products are registered, the quality of the circulating products is maintained.

Organogram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MRS TSIU
MS MOGATLE
PRINCIPAL PHARMACIST I
MR MAHUPU
MR BAKI
MR JOY
SENIOR PHARMACIST
VACANT
DR MODUTLWA
MS URIO
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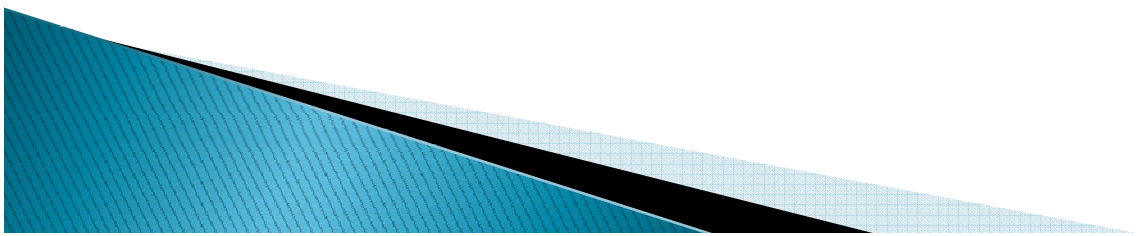
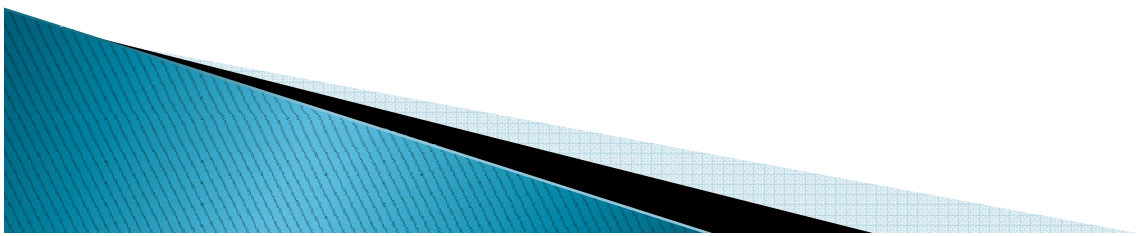
Functions of DRU

- Registration
  - Allopathic medicines
  - Complementary medicines
- Medicines control
  - Habit forming drugs (HFD)
  - Inspectorate
  - GMP inspections
  - Pharmacovigilance/Postmarketing surveilance



New medicine registration dossiers

- Receiving of application
- Pre-evaluation coding and entry into the database
- Assigning application numbers and acknowledging receipt to the applicant
- Evaluation/ Assessment
- Communication of queries to applicants



New medicine registration dossiers cont.

- Re-evaluation of resubmissions after queries are communicated to the applicants
- Pre registration discussions of the evaluation reports Preparation of reports for Drugs Advisory Board
- Registration/Rejection/Deferred with the Drugs Advisory Board
- Preparation of registration certificates and implementing other DAB decisions
- Communication with the applicants

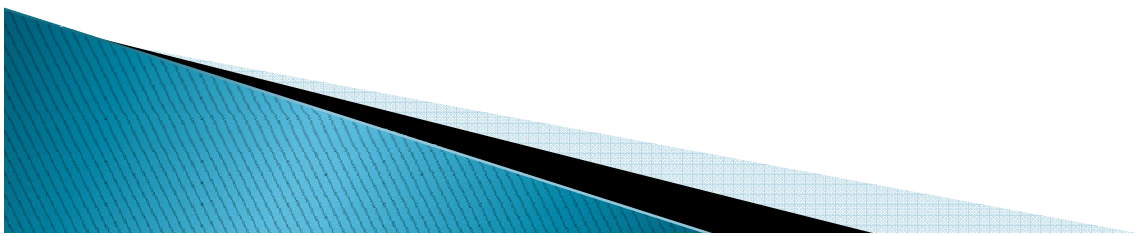
Variations

- Drugs Regulatory Unit of Botswana implemented variation guidelines in June 2009 so any application before this date were not processed.
- Variation applications are received and entered into SIAMED(an electronic database).
- The Evaluator, using the Variations guidelines, evaluates the application and prepares the letter which notes the queries in the application.
- The evaluator then gives the letter to a second evaluator who evaluates to check for grammar and scientific correctness.

Variations cont.

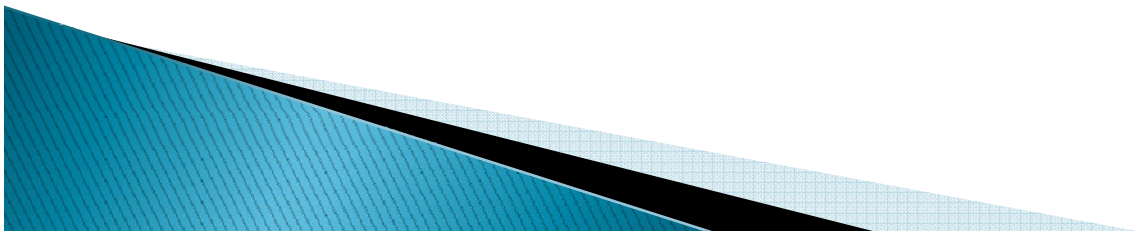
- Second evaluator comments on the letter.
- Second evaluator gives the first evaluator the letter for finalisation.

- The evaluator then sends the letter of queries to the applicant, within two weeks.
- Upon receiving an adequate response, update the blue book if it's a variation which requires update of the blue book.



Import Control

- Assist the Customs Officers at border controls to control import of medicines into the country.
- The responsibility of the unit is to vet all import requests from all importers to ensure that only medicines that are allowed into the country are imported

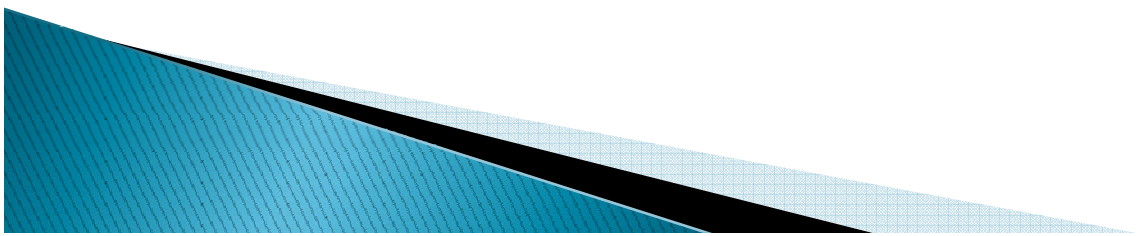


Pharmacovigilance

- Relatively new
- ADR monitoring
  - Developed tools to report and capture ADR reports (guideline report form)
  - Sensitization of stakeholders (potential reporters of ADR) 3/4 of the country
  - Data collection and processing
  - Report generation for submission to WHO
  - PMS plan is expected in the application.(Some companies are already reporting ADRs)

Exemptions

- Process requests for exemption from registration of medicines for therapeutic use.
- There are 400 applications per year and the activities involved include
  - Receipt of applications
  - Checking of registration status of the medicines
  - Evaluation of information provided
  - Communication with applicants
  - Regular meetings with border staff to impress the importance of allowing only registered medicines



Clinical Trials

- Receipt of applications
- Assessment of applications
- Preparation of reports for committee review
- Presentation of the recommendations to the DAB
- Monitoring of the trial as they commence
- No GCP inspections currently

Interventions

- In 2008 the DRU had a backlog of about 1500 applications, following the report by SCMS a retreat system was introduced to reduce backlog
- In December 2010, a new way of outsourcing for evaluation of applications was introduced which includes a component of transfer of skills and has a better monitoring system

Interventions cont.

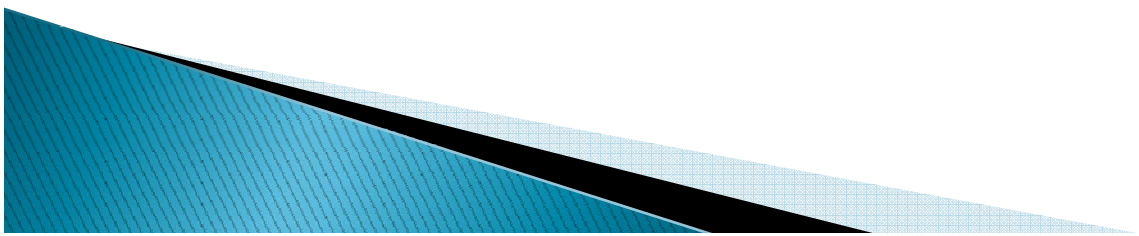
- Funds from other partners like PEPFAR have been used to train staff on evaluation of applications, use of SIAMED
- The Unit sought assistance from WHO Prequalification system to train staff members

Achievements

- As of April 2011 there are 160 applications pending evaluation compared to 1500 in 2007
- Currently there are 11 guidelines related to registration of medicines, compared to one guideline in 2008
- Applications are now submitted in CDs as well as one hard copy
- Improved quality of dossiers and reports

Achievements cont.

- Guidelines and application forms are now published on the Ministry of Health website
- SOPs are available for major activities
- A computer based registration system (SIAMED) is in use
- All dossiers are stored in dossier rooms which have the appropriate packaging and shelves



Achievements cont.

- A document management system (manual and computerized) is in place
- Registration certificates were issued from 2010
- A sample management system is in place. Samples are now being sent to the NDQCL for testing
- All registered products are now being monitored for variations

Challenges

- High attrition rate of staff
- Lack of experienced staff, majority of staff have less than two years experience
- Inadequate staff
- Establishing timelines due to lack of historical data
- Poor transport availability

Challenges cont.

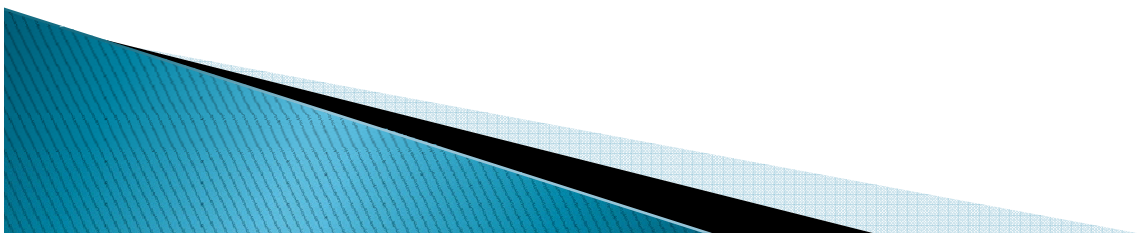
- Lack of funds to conduct Good Manufacturing Practice inspection on pharmaceutical manufacturers
- Lack of office space
- Lack of expertise for troubleshooting for the narcotics software
- The use of outdated legal framework in medicines regulation
- Challenges with transparency and efficiency of service delivery

Next Steps

- Update list of products allowed in Botswana
- Update and develop other guidelines
- Improve capacity of staff
- To monitor the quality of drugs as they enter the country.

Next Steps cont.

- Conduct two consultancies this financial year
- Update listed products
- Develop more guidelines
- Review system of recognizing registration from other countries



Questions

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