ZAMBIA MEDICINES REGULATORY AUTHORITY

OVERVIEW OF ZAMRA

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OUTLINE OF THE PRESENTATION

- **Background**
- **Organisational Structure**
- **Functions of ZAMRA**
- **Inspections**
- **Marketing Authorisation Activities**

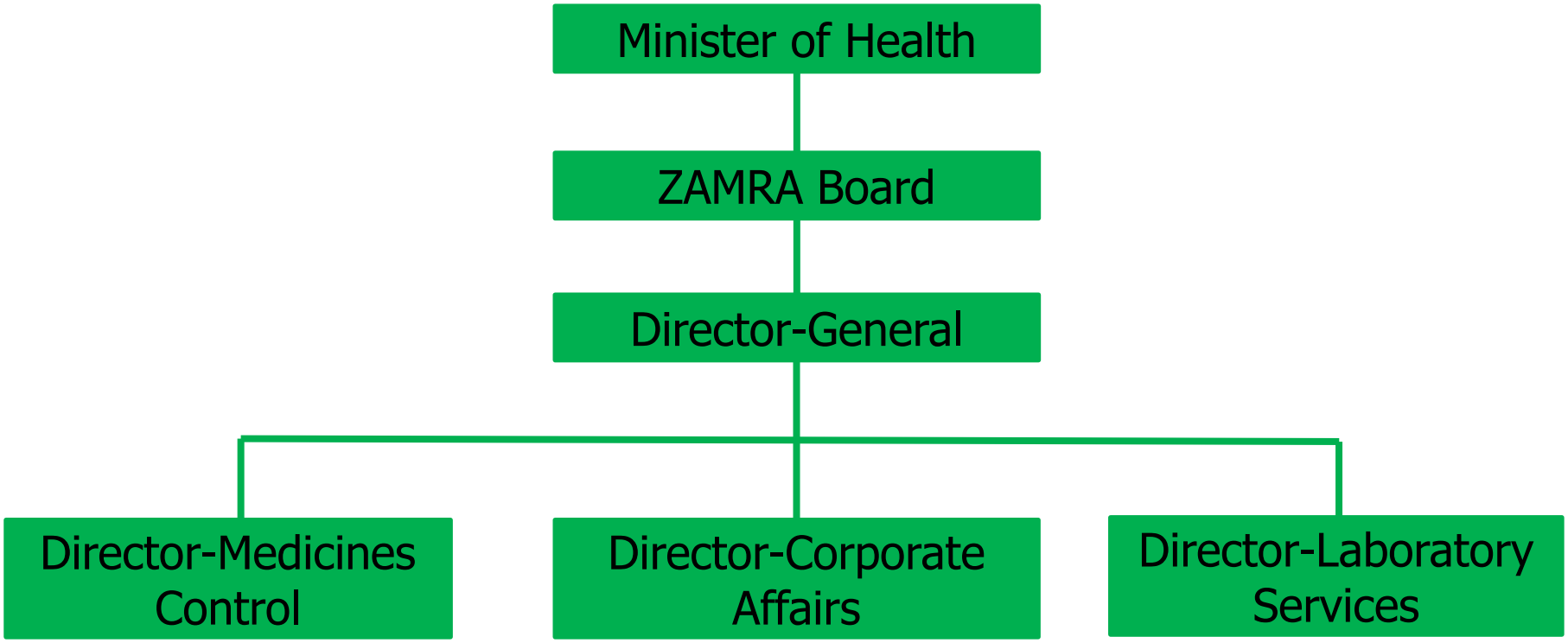
BACKGROUND AND LEGAL MANDATE

- Zambia Medicines Regulatory Authority (ZAMRA) is the Statutory body under the Ministry of Health.

- **ZAMRA draws its mandate from the Medicines and Allied Substances Act (No.3) of 2013**

- **Mandate covers:**
  - All Medicines and Allied Substances
  - All Distribution Channels in the Supply Chain of Medicines and Allied Substances (including manufacturers, importers, wholesalers, retailers and hospital pharmacies)

ORGANISATION STRUCTURE



FUNCTIONS OF ZAMRA

- Grant of Marketing Authorization of Medicines and Allied Substances
- Authorisation and monitoring of Clinical Trials involving medicines or allied substances
- Licensing of Pharmaceutical facilities
- Inspection of Pharmaceutical facilities
- Monitoring of Medicines or Allied Substances throughout the Supply Chain
- Quality control testing of Medicines and Allied Substances

LICENSING SURVEILLANCE AND ENFORCEMENT

SECTION

INSPECTIONS

- Part VIII of the Act empowers the Authority to undertake Inspections

- The following inspections are conducted:

- Pre-licensing (Licensing)
  - To support applications for licences, certificates or permits
  - Reports from these inspection inform the decision to issue or not issue licences, certificates or permits

- Post licensing (Regulatory)
  - Good Distribution Practices (GDP) Inspections
  - Good Manufacturing Practices (GMP) Inspections

INSPECTIONS - GDP

- Based on various regulations and Guidelines on Good Distribution Practices *(http://www.zamra.co.zm/wp-content/uploads/2017/08/GUIDELINES-ON-GOOD-DISTRIBUTION-PRACTICES.pdf)* published August 2017.

- Inspections are intended to ensure that Licence holders, Certificate holders and permit holders adhere to the terms and conditions

- Failure to adhere to conditions, depending on gravity may result in:
  - Counselling
  - Warning
  - Suspension
  - Revocation
  - Prosecution

INSPECTIONS - GMP

- Based on:
  - SI No 91 of 2018, Pharmaceutical License Regulations
  - WHO Guidelines (WHO TRS 986 Annex 2, and TRS 1019 annex 2)
- Focuses local and foreign based manufacturers
- Inspections are intended to ensure that License holders manufacture medicines based on current Good Manufacturing Practices
- Manufacturers are given an opportunity to make Corrective and Prevention Action (CAPAs) plans where they are found to be non-complaint.
- Failure to address deficiencies depending on gravity may result in:
  - Suspension Licence or Marketing authorisation for affected products
  - Revocation License or Marketing authorisation for affected products
  - Prosecution

LICENSING

The Authority grants the following Licenses, Certificates and Permits

- **Pharmaceutical License** for Wholesalers and Manufactures valid for 2 years (SI No 91 of 2018)
- **Certificate of Registration** for Retail and Hospital Pharmacies no limit to validity, subject or annual returns (SI No 58 of 2017)
- **Agro-veterinary Shop Permit** for Agro - veterinary Shops valid for 2 years (SI No 10 of 2016)
- **Health Shop Permit** for Health Shops valid for 2 Years (SI No 12 of 2016)
- **Dispensing Certificate** for Hospitals without Pharmacies valid for 2 years (SI No 11 of 2016)
- **Import and Export Permits** to facilitate importation or exportation of medicines, valid for one year for specific consignment (SI No 57 of 2017)

POST MARKETING SURVEILLANCE (PMS)

- Collects samples from the Market for testing at the NQDCL or other external laboratories
- Tests samples in the field using mini lab kits
- Investigation of complaints received pertaining to registered products
- Verification of compliance to:
  - labelling requirements (labels and package inserts)
  - standards of distribution channel systems
  - standards of pharmacy practice
  - approved advertisements and promotions of medicines
- Dissemination of drug information and promoting rational use of drugs/ public IEC on safe use of medicines
- Coordinates with WHO on substandard, spurious, falsely labeled, falsified and counterfeit (SSFFC) medical products
- Coordinates recalls whenever need arise

Recall Guidelines

- The guidelines for product recall/withdrawal are intended to assist members of the pharmaceutical industry i.e. the manufacturer, importer, distributor or marketing authorization holder of a medicine and/or allied substance in handling all aspects of product recall/withdrawal, including all corrections and removals; and thus, safeguard public health.

https://www.zamra.co.zm/wp-content/uploads/2023/08/Guidelines-on-Recall-of-Medicines-and-Allied-Substance.pdf

REGIONAL AND PORT OF ENTRY OFFICES

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Regional/sub-regional office are established as follows:

- Copperbelt Regional Office- Ndola
- Eastern Regional Office – Chipata
- Lusaka Regional Office- based at Head office
- Southern Sub regional Office – Livingstone
- Port of Entry at KKIA, Chirundu and Nakonde
- North-Western Regional Office – Solwezi
- Northern Regional Office - Kasama

Marketing Authorisation

1. MARKETING AUTHORISATION SECTION …cont'd

1) Marketing Authorisation Activities

2) Clinical Trial Activities

3) Vigilance Activities

Marketing Authorisation Activities

1) Legal Basis of Marketing Authorisation (MA)

- *Medicines and Allied Substances Act No. 3 of 2013*
- Section 39 of Part V of the Act provides for:
  - Prohibition of supply of medicines without MA
  - Requirement that applications for MA are made to ZAMRA in the prescribed manner
  - Sanctions and penalties for not complying with the Act.

2) Guidelines for Marketing Authorisation (MA)

- ZAMRA has implemented harmonised Common Technical Document (CTD) guidelines (since June 2015)
- Guidelines provide for:
  - Dossiers format (CTD)
  - Technical requirements (quality; clinical/ non-clinical data; templates
  - Bioavailability/Bioequivalence requirements
  - Number of samples (at least 2 in the smallest commercial pack)
- ZAMRA and Zazibona guidelines: http://www.zamra.co.zm/guidelines/
- Guidelines for WHO Collaborative process: https://extranet.who.int/prequal/content/collaborative-registration-faster-registration

Guidelines for Marketing Authorisation (MA)

- Various guidelines for grant of MA can be accessed on our website www.zamra.co.zm for the following product categories:
  - ZAMRA CTD Guidelines,
  - Human Medicines,
  - Veterinary Medicines,
  - Herbal Medicines and Nutritional supplements, Medical Devices,
  - In-Vitro Diagnostics,
  - Condoms
- New guidelines: Cosmetics, Tracking and Traceability

3) Classes of regulated medicines and allied substances

- Medicines for Human Use

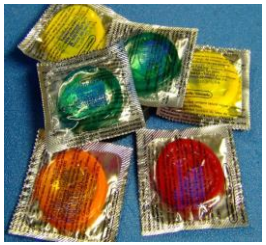
EXAMPLES

Chemical medicines, herbal medicines, biological drugs, vaccines …..

- Medicines for Veterinary Use

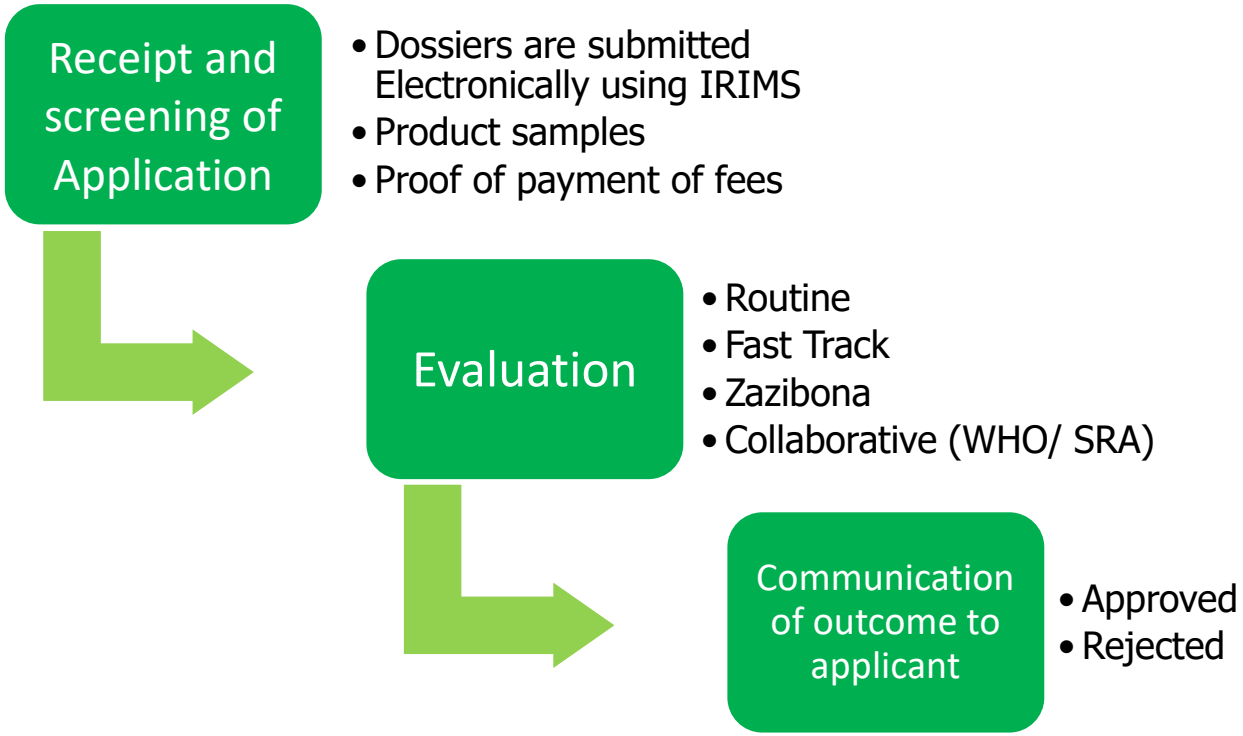
Chemical medicines, herbal medicines, biological drugs, vaccines …..

- Allied Substances



Arcaricides, cosmetics, disinfectants, food supplements, feed additives and supplements, medical and surgical sundries, medical devices and condoms…..

4) Marketing Authorisation Procedure



MARKETING AUTHORISATION ACTIVITIES

- Technical evaluation of:
  (i) product quality
  (ii) clinical/non-clinical and
  (iii) product information (SPC, PI and product labelling).

- An applicant is requested to make further clarifications or submit missing supporting documents, if required – two cycles of queries to respond within 120 days.

Evaluation of **quality, safety** & **efficacy**

RELIANCE REGISTRATION PROCEDURES

1. Zazibona Joint Assessment Procedure (SADC TWG)

- Submission of application to ZAMRA
- Joint review by SADC member countries
- Applications to be submitted to at least 2 active member states (NMRAs)
- Reports are shared with countries for decision making
- Website: https://Zazibona.com

2. WHO/ SRA Joint Collaborative Procedure

- Submission of application to ZAMRA
- Applicant expresses interest in writing to WHO prequalification
- WHO shares assessment and inspection reports with ZAMRA
- ZAMRA uses the reports for decision
- Website: https://extranet.who.int

MARKETING AUTHORISATION ACTIVITIES

Consideration of Applications by Technical Committee

- Guidelines and rationale for the new formulation/combination inform decision making.
- Possible outcomes include: Approval or Rejection.
- The Authority's decision is communicated to the prospective Marketing Authorisation Holder (MAH).

POST APPROVAL ACTIVITIES

- **Annual Retention** – mandatory payment of annual retention fees by Marketing Authorization Holders (MAHs), to keep the product on the register.
- **Amendment to MA** – in case of changes affecting approved products, MAH are required to apply to update the dossiers.
- **Renewal of Marketing Authorization** – requirement for MAH to apply for renewal of MA at the end of validity period of MA i.e. 5 years.
- **Post marketing surveillance and Vigilance**.

1) Legal Basis of Regulation of Clinical Trials

- Medicines and Allied Substances Act No. 3 of 2013
  - Sections 49 to 53 of Part VI of the Act provide for authorisation and monitoring of clinical trials
- The role of ZAMRA is to provide regulatory over sight on studies that involve medicines and allied substances and not ethical approval

4. VIGILANCE ACTIVITIES

1) Legal Basis of Regulation of Vigilance

- *Medicines and Allied Substances Act No. 3 of 2013*
  - Section 47 of Part V of the Act provides for making regulations for monitoring the safety of medicines and allied substances.
  - The day to day medicine safety monitoring activities are carried out through the National Pharmacovigilance Unit (NPVU) under ZAMRA, established in 2006.
  - Pharmacovigilance is based on spontaneous report

2) Guidelines for Vigilance

- Guidelines on Pharmacovigilance
- Pharmacovigilance Reference Manual
- Pharmacovigilance Training Manual - Facilitator's Guide
- Guidelines are available at: http://www.zamra.co.zm/guidelines/

THANK YOU FOR LISTENING!