MEDICINES REGULATORY AUTHORITY

The Medicines Regulatory Authority (MRA) is an autonomous body which was established by the Medicines and Related Substances Act (2013) to regulate

- Human and Veterinary Medicines
- Medical Devices
- Cosmetics

through the regulation and control of their production, importation, distribution and use.

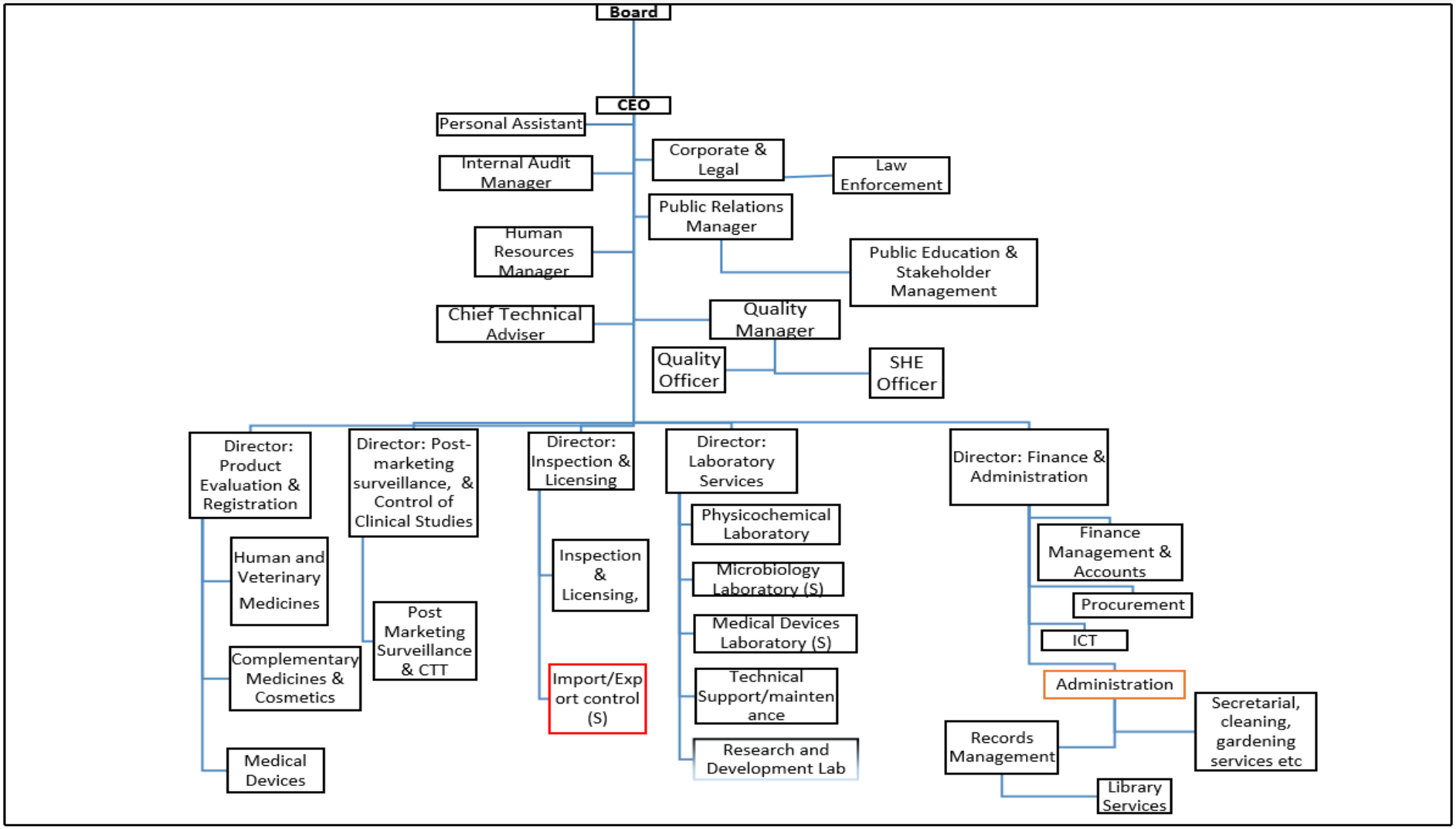
WHAT WILL CHANGE?

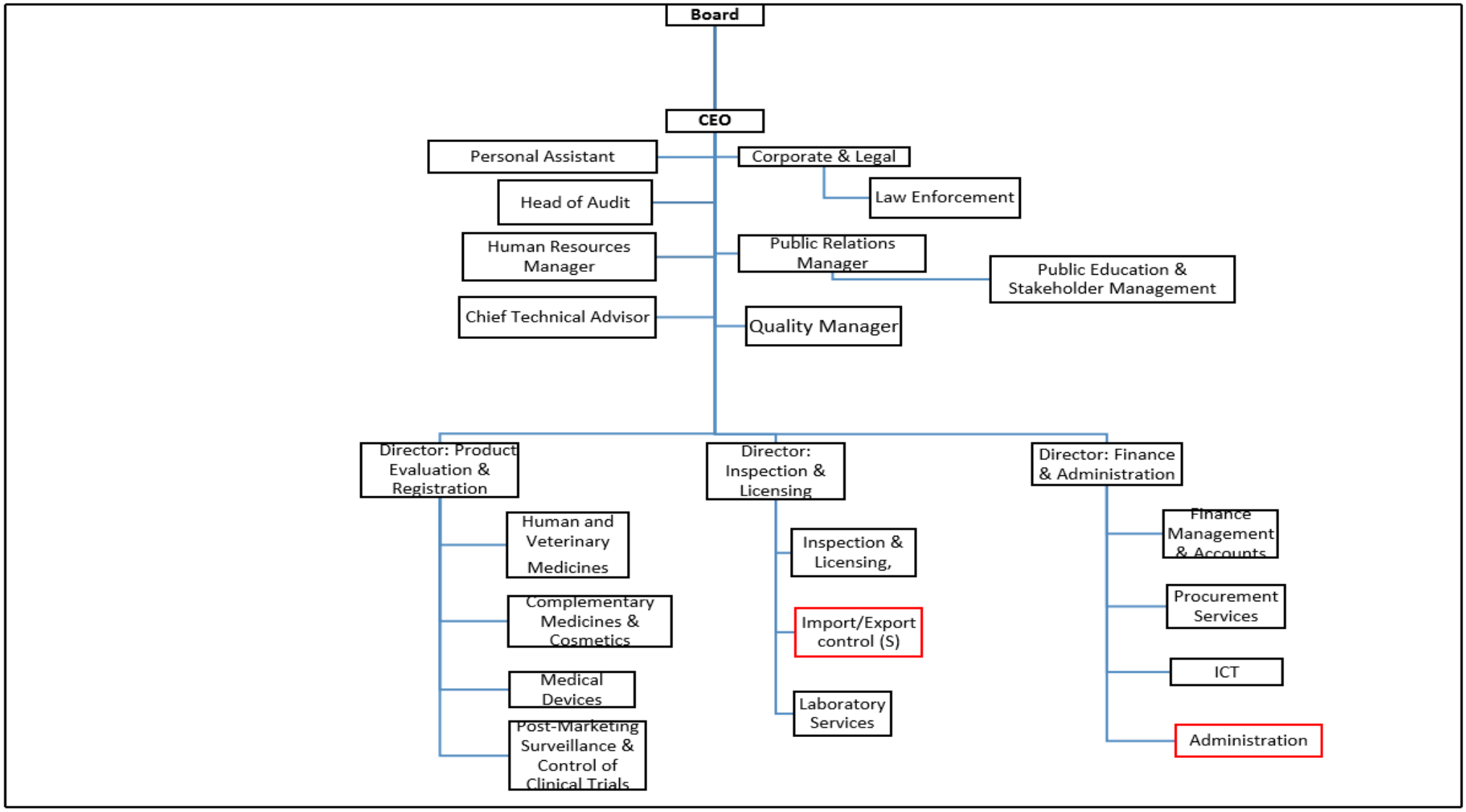
We have the ingredients

- Presence of the Act – implementation is Key
- Medicines control administration
  - organization and function
- Control and promote availability and marketing
  - registration, essential meds, PV, fees, special products etc
- Control of Supply
  - import/export
- Powers of Enforcement
  - appeals
  - legal procedures

THE AUTHORITY'S LOFTY GOALS

- Effective and facilitative regulation
- Improved capacity to improve community and consumer health and safety
- Household education and awareness
- Stakeholder coordination towards common goal
- Improved environment for pharmaceutical/medical industry growth (2 manu; 24 wholesalers; more than 110 pharmacies)
- Improve contribution to market access for meat exports


Board
CEO
Personal Assistant
Internal Audit Manager
Corporate & Legal
Law Enforcement
Public Relations Manager
Human Resources Manager
Public Education & Stakeholder Management
Chief Technical Adviser
Quality Manager
Quality Officer
SHE Officer
Director: Product Evaluation & Registration
Director: Post-marketing surveillance, & Control of Clinical Studies
Director: Inspection & Licensing
Director: Laboratory Services
Director: Finance & Administration
Human and Veterinary Medicines
Complementary Medicines & Cosmetics
Medical Devices
Post Marketing Surveillance & CTT
Inspection & Licensing,
Import/Export control (S)
Physicochemical Laboratory
Microbiology Laboratory (S)
Medical Devices Laboratory (S)
Technical Support/maintenance
Research and Development Lab
Finance Management & Accounts
Procurement
ICT
Administration
Secretarial, cleaning, gardening services etc
Records Management
Library Services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Human and Veterinary Medicines
Complementary Medicines & Cosmetics
Medical Devices
Post-Marketing Surveillance & Control of Clinical Trials
Inspection & Licensing,
Import/Export control (S)
Laboratory Services
Finance Management & Accounts
Procurement Services
ICT
Administration

LEADERSHIP PRIORITIES

- Strategy
  - Planning process to target data and information collection, and also direct and indirect community and industry stakeholders engagement
  - Aiming for sector-wide strategic inclusion.
  - Rollout to be integral to the MRA launch approximated before end of October 2018

- Competitive Expertise
  - Development of skills matrix: technical, managerial and leadership expertise
  - Leverage on collaborative partnerships
  - Targeted training at reputable organizations and authorities
  - Specialized knowledge and skills to increase laboratory capacity
  - Pharmacovigilance as a new and interesting area for capacity development
  - Medical devices regulation and veterinary products registration-technical capacity needs

ISSUES FOR BOMRA

- Dossier backlog
- Border controls and Import/Export Controls
- Alignment with other bodies such as Botswana Unified Revenue Service (BURS), Public Procurement and Asset Disposal Board (PPADB)
- Falsified medicines
- Counterfeit medicines (and other goods in general)
- Substance abuse
- Partnerships with other law enforcement agencies
- Local and cross-border partnerships for data & information sharing, including of PV importance
- Public education
- Introduction of Fees and Levies

Questions from Industry

- The questions are grouped according to subject matter and we have the following categories:
  - Suspension of receipt of applications
  - Dossier submission
  - Variations
  - Regulation of medical devices and complementary medicines
  - Labeling and promotions
  - Changes to guidelines and fees
  - Status of market authorisation, B listed products and exemptions
  - Harmonisation
  - General

Questions from Industry

- Suspension of receipt of applications
  - The transition from DRU to MRA is almost complete
  - Registration process was on-going during the suspension, addressing the backlog of applications
  - Changes will be communicated, the format is yet to be determined
  - The timelines will be re-visited and determined together with fees
  - It is expected that submission of applications will be resumed in the next few months

Questions from Industry

- Dossier submission
  - All along there was no delay in screening. The delay occurred beginning of 2017 leading to suspension of new applications. We do not anticipate delay of more than 2 months in future. CPP should be valid at the time of receiving an application.
  - Executed batch records are critical documents required as part of an application.
  - Application Form asks for Site Master File Number which might be useful for inspectors but submission of SMF is not necessary for assessment.
  - QOS is critical for generation of an assessment report. But section 3.2.R.2 Analytical Procedures & Validation Information Summaries is not critical for a full assessment. It is useful for abbreviated assessment.
  - At the time of suspension of applications we were receiving applications on CD-ROM only except for the application form. BoMRA is planning to have e-CTD but not yet

Questions from Industry

- Variations
  - There are different types of variations according to our guideline.
  - Major and minor variations need approval before implementation
  - Notifications may be implemented without prior approval

  - The review of variations is on-going

- Medical devices, complementary medicines & cosmetics
  - The Act provides for the regulation of all these in addition to medicines for humans and animals
  - Complementary medicines include herbal, homeopathic products, supplements and some vitamins in low doses
  - There are guidelines for registration of complementary medicines. There is a database of all complementary medicines allowed in Botswana. Guidelines for the other products are still to be developed. These will be communicated.

Questions from Industry

- Changes to guidelines and fees
  - Registration guidelines are not expected to change much, there may be updates from time to time
  - New guidelines will be developed for
    - Cosmetics
    - Medical devices
    - Veterinary medicines and medical products
  - Fees structure is under development and will cover a wide range of services provided. These will be published once approved and effective dates will be communicated

- Labeling and promotions
  - Multi market labels have been approved in the past provided they have English as one of the languages and covers all the areas specified in the law, regulations and guidelines.
  - ATC classification is not a deal breaker
  - Harmonisation of labeling is been discussed at SADC. It is expected that the working group will finalize the guidance document in the near future
  - All promotional and advertising materials must be approved by the MRA. Advertising to the public applies only to GSL medicines only, others may only be advertised to professional

Questions from Industry

- Status of market authorisation, B listed products and exemptions
  - The law states that MA is valid for five years.
  - DRU was not processing renewals; MA remained valid
  - Renewals will be required in future and a plan of action will be implemented to avoid being overwhelmed---this will be communicated in due course.
  - B listed products are those that were on the market before regulation, BOT products are those that have undergone registration process. They are both allowed to be marketed in the country
  - Since there was no application for the products, variations to these were not accepted, instead an application was required to be submitted with the variation. A different guideline was developed for these with fewer requirements
  - Exemptions are allowed for products required by patients in Botswana and are initiated by practitioners in BW

Questions from Industry

- Harmonisation
  - Botswana is part of the broader SADC harmonization agenda
  - At present the working initiative is the work sharing zazibona initiative. This includes joint inspections for application submitted through the initiative. There are no mutual agreements
  - SADC has a harmonization program that is part of the African Union agenda that is being planned, awaiting funding. This is aimed at building regulatory capacity within the region.

- Post market activities
  - Pharmacovigilance communication can be done via email.
  - Reports including PBRER may be submitted by email, however they may be too large in some instances and fail to be submitted.
  - BoMRA is setting up IT systems that will facilitate improved communications, including electronic submissions.

Questions from Industry

- General
  - Registration certificates will be issued in the near future.
  - Currently the list of registered products is not on the website, it can be obtained at a cost of P50.00
  - Direct face to face meeting have always been possible, one needs to make an appointment indicating the agenda for discussion
  - A question of discrepancies in approval letters was noted.
  - Sampling and bonusing are not provided for in our law so there is no guidance about those
  - Donations are provided for and there is guidance on donating.
    - There should be need for the product and unavailability of the product
    - For public sector the donation goes through Central Medical Stores
    - For private entities the importation is pre-authorized by MRA

- General
  - Biosimilar evaluations have not yet been conducted as there was no capacity at DRU but going forward the WHO guideline would be used by BOMRA.
  - Zazibona would be an excellent route to submit a biosimilar.
  - Previously no registrations for veterinary medicines but going forward BOMRA will have to implement a way forward for a smooth transition in order not to hamper access. Guidelines will be similar to human meds in terms of quality
  - Clinical Trials- Must be approved by Health research and development committee (HRDC) for science & ethics and MRA regulatory for product. HRDC gives authorisation.
  - Amendments approved by HRDC, except if it is about the product
  - ADR'S must be reported.
  - Safety updates for newer products must be submitted