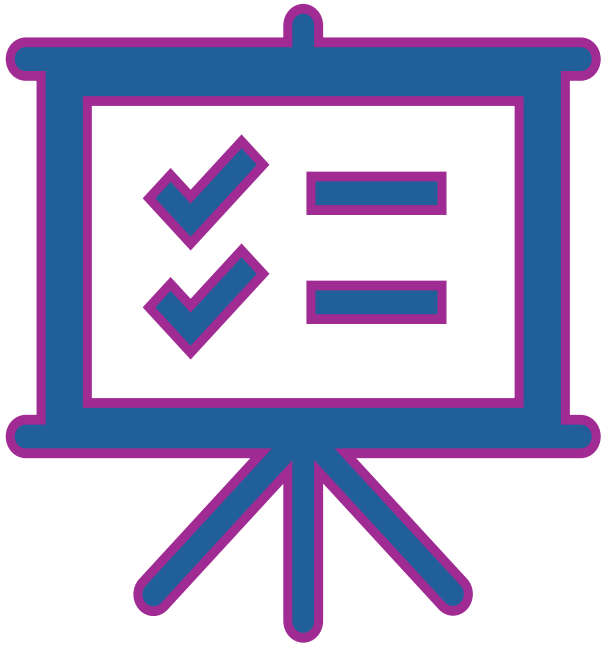
Implementation of Re-registration (MA Renewals) 2025 to 2027

Nenyasha Masangudza

Regulatory Officer (EVR)

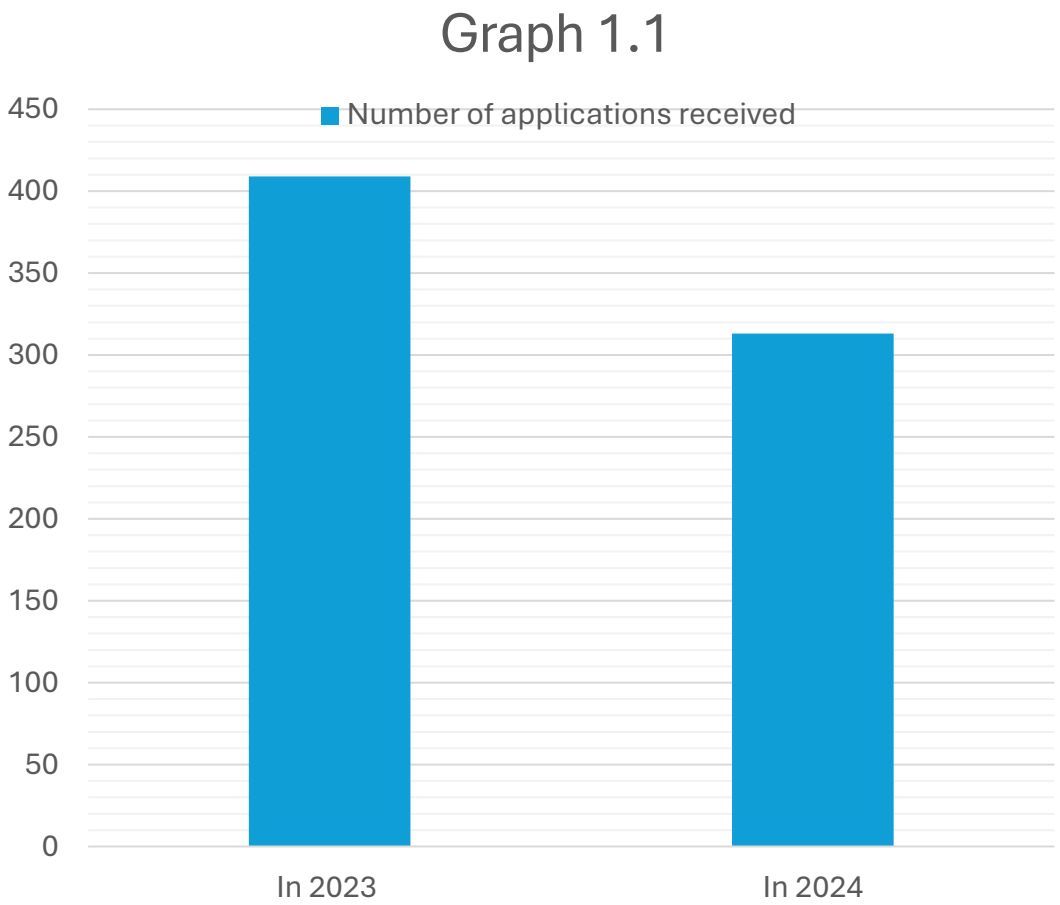


RECAP

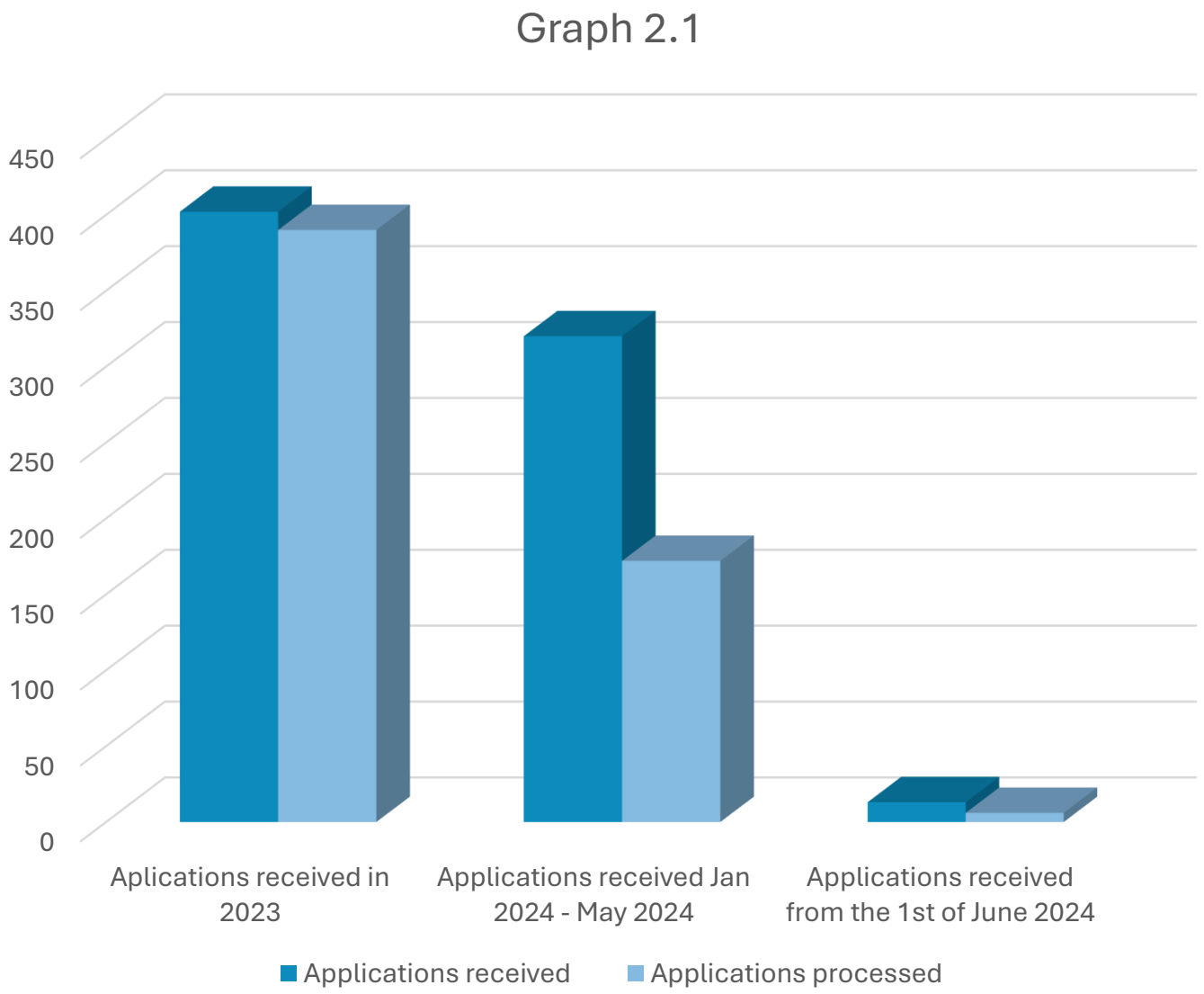
- This process came about as a **WHO-GBT** requirement for **NRAs** to **Renew** and or **Periodically Review** MA applications.
- Registration of a medicinal product is valid for a period of **five (5) years** unless the product is cancelled or suspended.
- The registration should therefore be renewed before the expiry of the validity period.
- A guideline on the renewal of product registration **(EVR-GL-06)** is available on the MCAZ website to assist applicants to prepare applications for renewal of product registrations .

Re-registration applications received 2023-2024

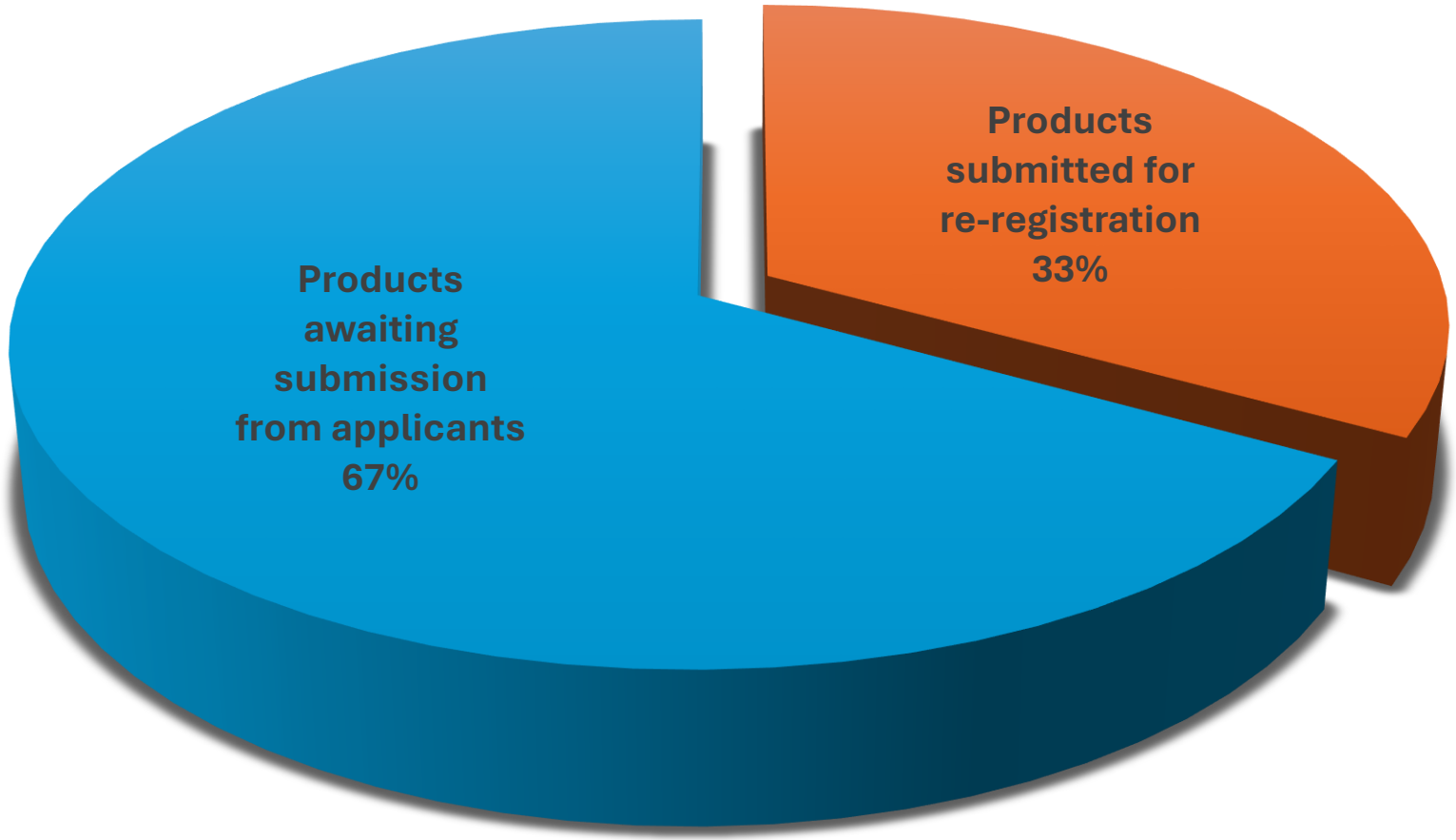
- **409** applications were received in **2023**
- **313** applications **2024**
- **332 applications** approved
- **185 applications** additional data request
- **44 applications** rejected



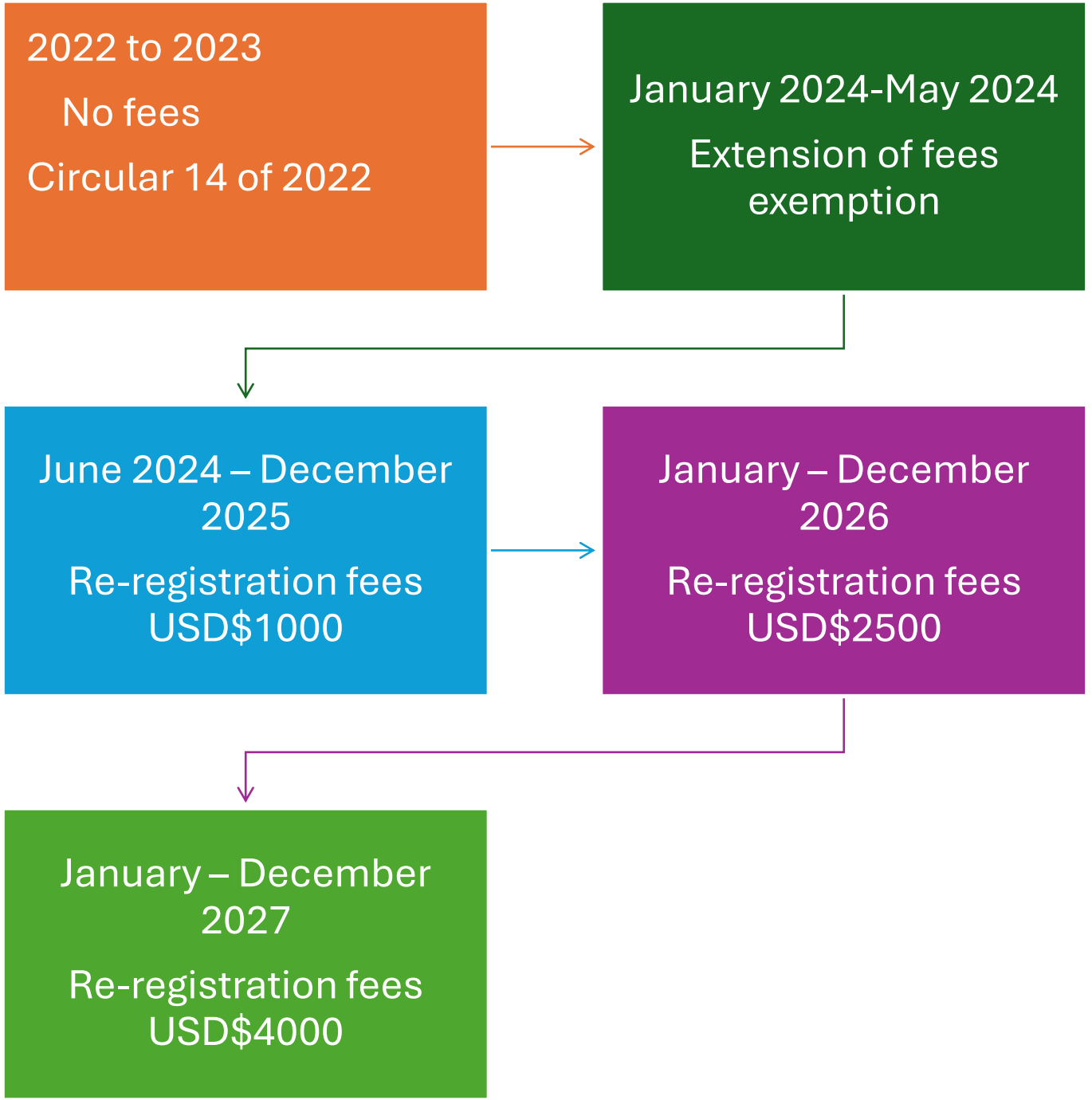
Applications received vs Applications processed since 2023



Applications received for re-registration are only 33.0% of the products only the register have been received



Fee schedule for re-registrations



Common deficiencies noted during re-registration evaluations

- Incomplete MC8 forms
- Labelling artworks
- Quality information summary in MS Word format
- Stability studies data

Applicants should provide current stability data showing the performance of the products manufactured post approval of the product registration.

- BMR’s for all the approved batch sizes

Noteworthy concerns

- A product cannot be renewed if it has been **cancelled or suspended**.
- No new variation submissions permitted
- Consolidated reports of variations must be submitted
- **Grossly deficient applications** are being **rejected** and should be resubmitted according to the EVR-GL-06.
- Applicants are **required to respond to queries** in time or the application will be **rejected**.


THANK YOU!