CUSTOMER SERVICE STANDARDS

BOMRA
MEDICINES REGULATORY AUTHORITY

GENERAL ADMINISTRATIVE SERVICES RESPONSE TIME

Tel

TELEPHONE ANSWERING: WITHIN 3 RINGS

LANGUAGE

ENGLISH & SETSWANA

24 Hours (External)

DAILY BUSINESS EMAIL COMMUNICATION

SOCIAL MEDIA, SMS / WHATSAPP QUERIES AND REQUESTS

3 Days (Turnaround time)

EMAIL QUERIES, COMPLAINTS AND REQUESTS

LETTER MAIL & FORMAL CORRESPONDENCES

MEDIA INQUIRIES, QUESTIONNAIRES & REQUESTS FOR INTERVIEWS

5 Days

PRO FORMA INVOICE FOR REGISTRATION FEES

FINANCE AND ADMINISTRATION:

- Open Tender: Requisition to Award Procurement:120 days
- Selective Tender: Requisition to Award rocurement:60 days
- Micro Procurement: Requisition to Award Procurement:5 days
- Payments to creditors 15th & 30th every month
- Contract Drafting Procurement & Legal: 14 days

TECHNICAL SERVICES TIMELINES

These timelines reflect the time that the application is at BoMRA and the applicant's time to respond to outstanding queries.

PRODUCT EVALUATION & REGISTRATION

REGISTRATION ASSESMENT PROCESS
Applicants will be given 2 cycles to respond to queries.

PHARMACOVIGILANCE & CLINICAL TRIALS :

- ADR reports: email, phone, Mobile App, Web
- Acknowledgement of receipt of the report:Response within 24 hours
- Approval of Clinical Trials — 90 Days
- Approval of Advertisement /Promotional Materials — 90 Days

REGISTRATION OF HUMAN MEDICINES:

	Screening For Applications:	WHO Collaborative Registration Procedure:	Normal process:	Expedited / Fast tracked products:	Products partly manufactured locally:	Products fully manufactured locally:
	2 Months	90 Days	36 months	12 months	24 months	18 months

REGISTRATION OF COMPLEMENTARY MEDICINES:

	Screening For Applications:	Normal process:	Expedited / Fast tracked products:	Products partly manufactured locally:	Products fully manufactured locally:
	2 Months	24 months	8 months	18 months	12 months

VARIATION FOR HUMAN MEDICINES:

- Notifications — 2 months
- Minor variations — 3 months
- Major variations — 4 months

EXEMPTION FROM REGISTRATION:

- 48 Hours
- Medical devices — 72 Hours

INSPECTION AND LICENSING:INSPECTION SERVICES

- 1. Inspection of Distributor/ retailer
- A new facility: 4 weeks
- Renewal: 6 weeks
- Expedited inspection: 2 weeks
- 2. Inspections of Manufacturers:
- a) Local manufacturer: 45 days
- b) International Manufacturer:100 days

IMPORT/EXPORT CONTROL SERVICES

- 1. Issuance of import/export permits for medicines:48hrs — 48 Hours
- 2. Issuance of import/export permits for samples:48hrs — 48 Hours
- 3. Issuance of transit permits:24hrs — 24 Hours
- 4. Issuance of permits for Narcotics, Psycho-tropics and precursor chemicals:48hrs
- 5. Issuance of import permits for cosmetics:48hrs — 48 Hours