STATUTORY INSTRUMENT NO. ___ OF 2026
MEDICINES AND RELATED SUBSTANCES ACT, 2025
(Act No. 29 of 2025)

MEDICINES AND RELATED SUBSTANCES (FEES, LEVIES AND PENALTIES) REGULATIONS, 2026

(Published on _____, 2026)

ARRANGEMENT OF REGULATIONS

IN EXERCISE of the powers conferred on the Minister of Health by sections 6(h), 26(1)(d), 26(1)(f) and 123 of the Medicines and Related Substances Act, 2025, after consultation with the Botswana Medicines Regulatory Authority, the following Regulations are hereby made—

PART I — PRELIMINARY

1. Citation and commencement

(1) These Regulations may be cited as the Medicines and Related Substances (Fees, Levies and Penalties) Regulations, 2026.

(2) These Regulations shall come into operation on such date as the Minister may, by notice published in the Gazette, appoint.

(3) Different dates may be appointed for different provisions or Schedules.

2. Interpretation

In these Regulations, unless the context otherwise requires—

"Act" means the Medicines and Related Substances Act, 2025;

"abridged pathway" means a regulatory pathway for products approved by recognised regulatory authorities with reduced evaluation requirements;

"administrative penalty" means a penalty imposed by the Authority without court proceedings for specified violations under section 119(i) of the Act;

"annual retention fee" means the fee payable annually to maintain a valid registration or licence;

"Authority" means the Botswana Medicines Regulatory Authority continued under section 5 of the Act;

"combined facility" means premises licensed for two or more regulatory activities under a single licence;

"compound penalty" means a penalty accepted by a person in lieu of prosecution for an offence under section 121 of the Act;

"expedited service" means priority processing of applications within reduced timelines for an additional fee;

"Fees Regulations" means these Regulations;

"full evaluation pathway" means a regulatory pathway requiring complete assessment of quality, safety and efficacy data;

"General Regulations" means the Medicines and Related Substances (General) Regulations, 2026;

"grouped application" means a single application covering multiple related products or variants;

"international applicant" means an applicant whose principal place of business is outside Botswana;

"levy" means a mandatory charge imposed to fund specific regulatory activities;

"line extension" means a variation to an existing product that requires a separate marketing authorisation;

"local applicant" means an applicant whose principal place of business is in Botswana, including companies incorporated in Botswana;

"local manufacturer" means an entity manufacturing regulated products wholly or partly within Botswana;

"notification pathway" means a simplified regulatory pathway for low-risk products;

"orphan medical product" means a medical product for rare diseases as defined in section 44 of the Act;

"recognised regulatory authority" means a regulatory authority recognised by the Authority for purposes of abridged or verification pathways;

"risk category" means the classification of a product or activity based on potential risk to public health;

"small-scale applicant" means a micro, small or medium enterprise as classified under relevant Botswana legislation; and, until such classification is prescribed, means an enterprise with an annual turnover not exceeding the threshold specified by the Authority by notice on its website

"stringent regulatory authority" means a regulatory authority that is a member, observer or associate of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use

"working day" means any day other than a Saturday, Sunday or public holiday in Botswana.

3. Application

(1) These Regulations apply to all fees, levies and penalties payable in connection with—

(a) registration of regulated products;
(b) licensing of operators;
(c) permits for import, transit, export and other activities;
(d) inspection services;
(e) laboratory services;
(f) other regulatory services; and
(g) penalties for violations.

(2) Product-specific regulations may prescribe additional fees not covered by these Regulations.

(3) Where there is conflict between these Regulations and product-specific fee provisions, these Regulations shall prevail unless the product-specific regulations expressly provide otherwise.

(4) In relation to cosmetic products, only the fees expressly designated for cosmetics in these Regulations and the Schedules shall apply, and Part VIII (Levies), regulation 27 (clinical trial authorisation fees) and regulation 34 (clinical trial site inspection fees) shall not apply to cosmetic products.

PART II — GENERAL PROVISIONS ON FEES

4. Fees payable

(1) The fees set out in Schedules 1 to 15 are payable for the applications, services, licences, permits, certificates and other matters specified therein.

(2) Fees may be charged based on—

(a) whether the applicant is a local or international applicant;
(b) the regulatory pathway applicable;
(c) the risk classification of the product, establishment or regulated or activity;
(d) whether the product is locally manufactured;

(e) whether expedited service is requested; and

(f). such other factors as may be prescribed by the Authority and published in the applicable fee schedule

(3) No application shall be processed until the prescribed fee has been paid in full, unless a fee waiver or deferment has been granted under regulation 7.

(4) The Authority shall publish a consolidated fee schedule on its website and update it whenever fees are amended.

(5) The Authority may apply grouped-application and bulk-submission discounts, as set out in the Schedules, where multiple related applications or notifications are submitted by the same applicant within a period specified in guidelines.

5. Payment methods

(1) Fees, levies, administrative penalties and compound penalties shall be paid by—

(a) electronic funds transfer to the Authority's designated bank account

(b) credit or debit card through the Authority's payment portal;

(c) mobile money platforms approved by the Authority; or

(d) any other method approved by the Authority and published on its website.

(2) Proof of payment shall—

(a) accompany every application;

(b) include the applicant's name and application reference number;

(c) be verifiable by the Authority; and

(d) be retained by the applicant for a period of not less than five years.

(3) Where payment is made from outside Botswana—

(a) all bank charges shall be borne by the applicant;

(b) the full fee must be received by the Authority; and

(c) payment shall be made in the currency specified or its equivalent.

6. Currency provisions

(1) Fees for international applicants are expressed in United States Dollars in the Schedules.

(2) Fees for local applicants are expressed in Botswana Pula in the Schedules.

(3) Where payment is made in a currency other than that specified—

(a) the exchange rate shall be the Bank of Botswana rate on the date of payment;

(b) the applicant shall ensure the full equivalent amount is received by the Authority; and

(c) any shortfall must be paid before processing commences.

(4) All fees are exclusive of—

(a) Value Added Tax, where applicable;

(b) bank charges; and

(c) any other applicable statutory levies.

7. Fee waiver and reductions

(1) The Authority may at its discretion grant a full or partial fee waiver from, or reduction of, any fee payable under these Regulations where—

(a) the product is intended for a Government health programme or public health emergency response;

(b) the product is a donation authorised under the General Regulations and intended for humanitarian purposes;

(c) the product is an orphan medical product within the meaning of section 44 of the Act;

(d) the applicant is a small-scale applicant, in respect of the fee categories specified in the Schedules;

(e) the applicant is a local manufacturer qualifying for an incentive under regulation 19 or regulation 31; or

(f) the Authority determines, on written application and for reasons recorded, that payment of the full fee would be contrary to the public interest or would unduly restrict access to essential medical products.

(2) An application for an exemption, reduction, waiver or deferment shall be made in writing to the Chief Executive Officer, stating the grounds relied upon and accompanied by supporting information.

(3) The Authority shall determine an application under subregulation (2) within thirty working days and shall communicate the decision, with reasons, to the applicant.

(4) The Authority shall maintain and publish criteria for waivers and reductions in guidelines, and shall report annually on exemptions granted.

(5) An exemption or reduction granted under this regulation may be withdrawn where it was obtained on false or misleading information, and the full fee shall thereupon become payable.

8. Refund policy

(1) Fees paid are generally non-refundable.
(2) A refund may be granted where—

> (a) the Authority is unable to provide the service applied for; or(b) a fee has been paid in error or in excess; or (c) the application is withdrawn in writing before evaluation or inspection has commenced.

(3) Where a refund is approved as per 2(c) above—

(a) an administrative charge of ten per cent shall be retained for applications withdrawn ;

(4) A refund request shall be made in writing within thirty days of the event giving rise to the request.

9. Annual review mechanism

(1) The Authority shall review all fees annually, considering—

(a) changes in the Consumer Price Index;

(b) the actual cost of providing regulatory services;

(c) regional and international fee benchmarks;

(d) stakeholder capacity to pay;

(e) public health objectives;

(f) the need to encourage local manufacturing; and

(g) sustainability of the Authority's operations.

(2) Proposed fee adjustments exceeding ten per cent shall be subject to stakeholder consultation for not less than thirty days.

(3) Fee adjustments shall—

(a) be published in the Gazette;

(b) be posted on the Authority's website at least sixty days before taking effect;

(c) take effect from 1st April each year, or such other date as may be determined; and

(d) not apply to applications submitted before the effective date.

(4) The Minister may, by statutory instrument, amend the Schedules to these Regulations.

(5) The Authority shall publish on its website the methodology, cost analysis and benchmarking outcomes underpinning each annual fee review, before any fee adjustment takes effect.

PART III — PRODUCT REGISTRATION FEES

10. Human medicines registration fees

(1) Fees for registration of human medicines are set out in Schedules 4 and 5.

(2.) Reduced fees apply for products manufactured locally and orphan medical products, 11. Veterinary medicines registration fees

(1) Fees for registration of veterinary medicines are set out in Schedules 4 and 9.

(2) The fee structure makes provision for vaccines and biologicals, antimicrobials subject to stewardship programmes, products for food-producing animals requiring residue data, and medicated feed premixes.

12. Medical devices registration fees

(1) Fees for registration of medical devices, including in-vitro diagnostics, are set out in Schedule 4.

(2) Fees are differentiated by risk classification: Class A (low risk) notification pathway fees; Class B (low-moderate risk) standard evaluation fees; Class C (moderate-high risk) enhanced evaluation fees; and Class D (high risk) full evaluation fees.

(3) Grouped application discounts apply where multiple variants of the same device family are submitted at the same manufacturing site with the same intended use and risk classification.

13. In-vitro diagnostics registration fees

(1) Fees for registration of in-vitro diagnostic medical devices are set out in Schedules 6 and 7 and are differentiated by risk classification in the same manner as medical devices.

14. Blood and blood products fees

(1) Fees for blood and blood products are as prescribed by the applicable regulations. Reduced fees apply for public sector blood establishments.

15. Complementary medicines registration fees

(1) Fees for complementary medicines are set out in Schedules.

16. Cosmetics notification and registration fees

(1) Fees for cosmetics are set out in Schedules. Fee levels differentiate between notification for general-use cosmetics and registration for special-use cosmetics.

17. Traditional medicines registration fees

(1) Fees for traditional medicines are as prescribed by the applicable product regulations. Simplified registration pathways and reduced fees support indigenous knowledge holders and traditional health practitioners.

18. Orphan medical products fee provisions

(1) Reduced fees, as set out in the respective Schedules, apply to the registration, variation, renewal and retention of orphan medical products designated under section 44 of the Act.

(2) The Authority may waive the registration fee entirely where the orphan medical product addresses a condition for which no registered alternative exists in Botswana.

(3) An applicant seeking orphan fee treatment shall provide evidence of orphan designation or of eligibility for such designation with the application.

PART IV — LICENSING FEES

19. Manufacturing facility licensing fees

The fees payable in respect of the licensing, renewal, and variation of domestic manufacturing facilities shall be as set out in Schedule 2, differentiated according to the type of products manufactured, the scale of operations, and whether manufacturing involves sterile or non-sterile processes, provided that—

- (a) the fees prescribed in Schedule 2 shall apply only to local manufacturers; and
- (b) a full fee waiver shall apply to local manufacturing facilities establishing operations in Botswana for the first time, in support of citizen economic

empowerment and the development of domestic pharmaceutical production capacity

20. Import and export licensing fees

(1) The fees payable in respect of the grant, renewal and variation of import and export licences are set out in Schedule 2. Fees for consignment-specific import, export and transit permits are set out in Schedule 3 and are dealt with under Part V.

21. Wholesale and distribution licensing fees

(1) The fees payable in respect of the licensing, renewal, and variation of wholesale, distribution, storage, and other supply chain operations relating to regulated products shall be as set out in Schedule 2..

22. **Retail and dispensing licensing fees**

(1) Retail and dispensing licensing fees are set out in **Schedule 2.** Categories include community pharmacies, hospital pharmacies, veterinary pharmacies, dispensaries, authorised health facility dispensaries, and group practice pharmacies.

23. Blood establishment licensing fees

(1) Blood establishment licensing fees are as prescribed by the applicable regulations.

24. Special purpose licensing fees

(1) Special purpose licensing fees, including for authorised premises and cosmetics operations, are set out in Schedule 2.

PART V — PERMIT AND SERVICE FEES

25. Import and export permit fees

(1) Import and export permit fees as well as importation invoice fee for all registered or listed products and unregistered products are set out in Schedule 3. The letter of authorisation fee is as set out in Schedule 3.

(2) The Authority may issue an annual or consolidated import permit covering multiple consignments of routinely imported registered products, on payment of the consolidated permit fee set out in Schedule 3, subject to conditions specified in guidelines.

26. Transit permit fees

(1) Transit permit fees are set out in Schedule 3.

27. Clinical trial authorisation fees

(1) Clinical trial authorisation fees are set out in Schedule 5. Reduced fees apply for locally-sponsored trials, trials addressing local health priorities, academic and investigator-initiated trials, and trials in collaboration with Government. Amendment fees are lower than initial application fees.

28. Advertising approval fees

(1) Advertising approval fees are set out in Schedule 6. Fees are differentiated by media type and whether the applicant is an international or local applicant.

29. Laboratory services fees

(1) Laboratory testing fees shall be as determined and published by the Authority from time to time.

30. Certificate and document fees

(1) Certificate and document fees are set out in Schedules. Categories include Certificate of Pharmaceutical Product, Free Sale Certificate, Good Manufacturing Practice Certificate, and other letters of authorisation or confirmation.

PART VI — INSPECTION FEES

31. Good manufacturing practice inspection fees

The fees payable in respect of good manufacturing practice inspections shall be as set out in Schedule 1, provided that—

- (a) fees for inspection of foreign manufacturing sites shall be differentiated by geographic location as prescribed in Schedule 1;
- (b) fees for inspection of local manufacturing sites shall be as prescribed in Schedule 1, differentiated by the type of products manufactured and whether manufacturing involves sterile or non-sterile processes;
- (c) additional fees shall apply in respect of—
    - (i) additional manufacturing blocks or production lines at the same site;
    - (ii) re-inspection necessitated by significant non-compliance findings; and
    - (iii) expedited inspection scheduling at the request of the applicant;
- (d) where an on-site inspection is not required, desk review fees as prescribed in Schedule 1 shall apply in lieu of inspection fees; and
- (e) reduced fees shall apply where—
    - (i) the site holds a current good manufacturing practice certification issued by a recognised and listed regulatory authority;
    - (ii) the inspection is conducted jointly with another regulatory authority;
    - (iii) the application is processed through a reliance pathway recognised by the Authority; or
    - (iv) the site is a local manufacturing facility undergoing its first good manufacturing practice inspection, in support of citizen economic empowerment and the development of domestic pharmaceutical production capacity.

32. Good distribution practice inspection fees

(1) The fees payable in respect of good distribution practice inspections of wholesale, distribution, storage and transportation operations shall be as set out in Schedule 1, differentiated by the scale and risk classification of the operation.

(2) Reduced fees shall apply where the operation holds a current good distribution practice certification issued by a recognised regulatory authority, or where the inspection is conducted through a reliance pathway recognised by the Authority.

(3) Re-inspection fees shall apply where a further inspection is necessitated by significant non-compliance findings.

33. Blood establishment inspection fees

(1) Blood establishment inspection fees reflect the complexity and scope of the establishment's operations. Public sector facilities receive reduced inspection fees.

34. Clinical trial site inspection fees

(1) The fees payable in respect of the inspection of clinical trial sites, including good clinical practice inspections of investigator sites, sponsor facilities and contract research organisations, shall be as set out by the authority..

(2) Reduced fees shall apply for locally-sponsored trials, academic and investigator-initiated trials, and trials conducted in collaboration with Government.

(3) This regulation does not apply to voluntary studies conducted in respect of cosmetic products.

35. Special inspection fees

(1) The fees payable in respect of special inspections shall be as set out in Schedule 1, and shall apply to—

(a) for-cause inspections triggered by complaints, adverse events, or suspected non-compliance, provided that where significant non-compliance is confirmed, the cost of the inspection shall be recoverable from the person inspected;

(b) follow-up and verification inspections;

(c) pre-approval inspections requested by an applicant; and

(d) joint inspections with other regulatory authorities, in respect of which the Authority may apportion fees.

(2) No fee shall be payable by the person inspected in respect of a routine risk-based surveillance inspection initiated by the Authority, or a for-cause inspection in which no significant non-compliance is found.

PART VII — POST APPROVAL FEES

36. Annual retention fees

(1) Annual retention fees to maintain valid registrations are set out in the respective Schedules.

(2) Retention fees are due on the anniversary of the date of initial registration.

(3) A grace period of thirty days shall apply before late payment penalties accrue.

(4) Failure to pay retention fees for ninety days shall result in suspension of registration.

37. Variation fees

(1) Variation fees are set out in the respective Schedules. Fees are differentiated by variation type: major variations attract the highest fees for changes with potential significant impact on quality, safety or efficacy; minor variations attract moderate fees for changes with limited impact; and notifications attract the lowest fees.

38. Renewal fees

(1) Renewal fees for registrations and licences are set out in the respective Schedules. Expedited renewal fees apply where late submission necessitates priority processing.

(2) Failure to pay renewal fees ninety days after expiry of marketing authorization shall result in suspension of registration.

PART VIII — LEVIES

39. Regulatory levy

(1) A regulatory levy of 0.5 per cent of the cost, insurance and freight value of imported regulated products shall be payable to support the regulatory operations of the Authority.

(2) The levy shall be—

(a) collected at the point of import;

(b) remitted to the Authority on a monthly basis; and

(c) reported by importers in monthly returns.

(3) Exemptions from the regulatory levy apply to products imported for Government programmes, humanitarian donations, and products imported for re-export.

(4) The levy rate may be reviewed annually by the Minister.

(5) The regulatory levy is distinct from, and in addition to, the consignment-specific permit fees set out by the authority , and the Authority shall publish annually a consolidated statement of the effective aggregate charge on imported regulated products, including all applicable fees and levies.

40. Pharmacovigilance levy

(1) Marketing authorisation holders shall pay an annual pharmacovigilance levy to support the national vigilance programme established under section 71 of the Act.

(2) The pharmacovigilance levy shall be calculated at the rate, and payable at the times, set out in Schedule 15, and shall be applied exclusively to the funding of the national vigilance programme.

(3) The Authority shall account separately for levy income and shall report annually on its application.

(4) This regulation does not apply to cosmetic products.

PART IX — PENALTIES AND SANCTIONS

42. Late payment penalties

(1) Late payment penalties apply to overdue fees to late payments of regulatory fees as follows—

Days Overdue	Penalty
-30 days	Warning
31–60 days	10% of outstanding amount
61–90 days	20% of outstanding amount
Over 90 days	Suspension of registration or licence, plus 30% penalty

(2) Late penalties are in addition to, and not in substitution for, any other sanction under the Act.

43. Administrative penalties

(1) The following administrative penalties may, together with other regulatory sanctions,be imposed by the Authority for the specified violations—

Violation	Maximum Penalty (BWP)
Operating without a valid license	500,000
Supplying unregistered and/or unauthorized products	1,000,000
Exports, imports, distributions manufactures, advertises, promoting, dispensing or stores or sale of substandard or falsified products	1,000,000
Sale of or in possession for purposes of sale of expired medicines	5,000,000
Tampering with products under quarantine	5,000,000

Failure to meet consignment verification requirements at ports of entry e.g., PSI requirements	5,000,000
Violation of licensing requirements	1,000,000
Violation of conditions of an import/export/transit permit	5,000,000
Disposal of expired, unregistered and/or unauthorized products	Cost incurred for disposal
Imports or exports a prohibited regulated product	5,000,000
Failure to meet packaging and labelling requirements	1,000,000
Failure to maintain adequate records	250,000
Obstruction of an inspector	300,000
Failure to report adverse events	200,000
Failure to submit required reports	150,000
Advertising without approval	1,000,000
Breach of data protection obligations	200,000
Falsifying of documentation representing The Authority	5,000,000
Impersonating an employee of The Authority or any other person delegated duties of The Authority	5,000,000

(2) Repeat violations may attract a prescribed fine as outlined in the relevant guideline.

(3) Administrative penalties may be appealed to the Board within thirty days of imposition.

(4) Imposing an administrative penalty does not preclude criminal prosecution for the same conduct.

44. Compound penalties

(1) In accordance with section 121 of the Act, the following offences may be compounded—

Offence	Maximum Compound Amount (BWP)
Advertising without approval	500,000
Minor labelling violations	250,000
Failure to notify the Authority on Cosmetics products placed in the supply chain	250 000
Minor record-keeping violations	100,000
Manufacturing, selling, supply, export, import, distribute, dispensing, storage of regulated products without Authorisation	500,000
Failure to submit required reports	75,000
Late renewal applications	50,000

First-time import documentation violations	250,000
Minor premises compliance issues	150,000
Failure to submit required reports	100,000

(2) Compound amounts shall not exceed fifty per cent of the maximum fine for the relevant offence under the Act.

(3) Serious offences involving falsified products, controlled substances, or deliberate deception are not compoundable.

(4) The procedure for compounding requires the person to admit the offence in writing, the compound offer to be made before the commencement of court proceedings, payment to be made within thirty days of the offer, and failure to pay within the specified period shall result in prosecution.

45. Risk-based penalty framework

(1) The Authority shall determine administrative penalties using a risk-based approach that considers the following factors—

- (a) the potential for harm to patients;
- (b) the size of the population exposed to the violation;
- (c) whether the violation was intentional or negligent;
- (d) the duration of the violation; and
- (e) the ease or difficulty of detecting the violation.

(2) **For the purposes of subregulation (1), the Authority shall apply penalty levels as follows—**

- (a) where the risk assessment yields a high risk score, the maximum prescribed penalty range shall apply;
- (b) where the risk assessment yields a medium risk score, the mid-range prescribed penalty shall apply; and
- (c) where the risk assessment yields a low risk score, the minimum prescribed penalty range shall apply.

(3) The Authority shall take into account the following mitigating factors when determining the appropriate penalty—

- (a) voluntary disclosure of the violation by the regulated entity;
- (b) prompt corrective action taken upon discovery of the violation;

- (c) cooperation with the Authority's investigation;
- (d) absence of prior violations;
- (e) demonstrated good faith efforts to comply with applicable requirements; and
- (f) documented financial hardship of the regulated entity.

(4) The Authority shall take into account the following aggravating factors when determining the appropriate penalty—

- (a) repeated violations of the same or similar nature;

(b) vulnerability of the population affected by the violation.

(5) The Authority shall issue Guidelines prescribing the risk scoring methodology, score ranges, corresponding penalty bands, and procedures for applying mitigating and aggravating factors under this regulation and may review and amend such Guidelines as circumstances require.

(6) In the case of a first-time administrative contravention that is minor, unintentional and promptly remediated, the Authority shall, before imposing a financial penalty, consider issuing a written warning or compliance notice requiring corrective action within a specified period.

PART X — TRANSITIONAL AND FINAL PROVISIONS

46. Transitional provisions

(1) Fees paid under the repealed regulations before the commencement of these Regulations shall remain valid for the period for which they were paid.

(2) Applications submitted before commencement shall be processed under the fee structure in force at the date of submission.

(3) Where new fees represent an increase of more than fifty per cent over previous fees—

(a) the increase shall be phased over two years;

(b) in year one, the fee payable shall be the previous fee plus fifty per cent of the increase; and

(c) in year two, the full new fee shall apply.

(4) Registrations and licences valid at the date of commencement shall continue with existing fee obligations until renewal.

47. Repeal

The fees and penalties provisions in the Medicines and Related Substances Regulations, 2019, are hereby repealed.

Made this _____ day of _____, 2026

_____

Minister of Health

SCHEDULE 1

GMP COMPLIANCE FEES

1.1. Application for cGMP (Medicines) Inspection

GMP Inspection	Fee (USD)
SADC	3 500
REST OF AFRICA	5 000
ASIA	6 500
REST OF THE WORLD	7 000
Desk review	3 500
Additional - Onsite Inspection, Extra manufacturing block (each)	1 000
Additional - Desk review, Extra manufacturing line (each)	1 000
Expedited	
SADC	7 000
REST OF AFRICA	10 000
ASIA	13 000
REST OF THE WORLD	14 000

1.2. Application for Quality Audit (Medical Devices)

Quality Audit	**Fee (USD)**
SADC	3 500
REST OF AFRICA	5 000
ASIA	6 500
REST OF THE WORLD	7 000
Desk review	3 500
Additional - Onsite Inspection, Extra manufacturing block (each)	1 000
Additional - Desk review, Extra manufacturing line (each)	1 000
Expedited	
SADC	7 000

REST OF AFRICA	10 000
ASIA	13 000
REST OF THE WORLD	14 000

SCHEDULE 2

LICENSING FEES

2.1. Local Manufacturer Licensing — New Premises and Renewals

Licensing fees – Non-Sterile	**Fee (BWP)**
cGMP - Full Manufacturing	Fee Waived
cGMP - Part Manufacturing	10 000
Re-inspection	5 000
Annual Manufacturing License	500
Licence variation	250
Expedited	
cGMP - Full Manufacturing	5 000
cGMP - Part Manufacturing	20 000
Licensing fees – Sterile	
cGMP - Full Manufacturing	Fee Waived
cGMP - Part Manufacturing	10 000
Re-inspection	7 500
Annual Manufacturing License	500
Licence variation	250
Expedited	
cGMP - Full Manufacturing	5 000
cGMP - Part Manufacturing	20 000
Licensing Fees – Medical Devices	
cGMP - Full manufacturing	Fee Waived
cGMP - Part manufacturing	10 000
Re-inspection	5 000
Annual manufacturing License	500
Licence variation	250
Expedited	
cGMP - Full manufacturing	5 000
cGMP - Part manufacturing	20 000

2.2. Other Pharmaceutical Operations — New Premises

Activity	**Fee (BWP)**
Distributor / Wholesaler - Medicines and Medical Devices	5 500
Retailer (Pharmacy dispensary, agriculture shops, Vet Clinics)	4 500
Pharmacy - Within Group Practice	4 500
Institutional Dispensary - Medicines and Medical Devices	2 500

Expedited	
Distributor / Wholesaler - Medicines and Medical Devices	11 000
Retailer (Pharmacy dispensary, Agric Shops, Vet Clinic)	9 000
Pharmacy - Within Group Practice	9 000
Institutional Dispensary - Medicines and Devices	5 000
Authorised Premises	
- Medium to Large Scale	500

2.3. Licensing Renewal

Activity	**Fee (BWP)**
Distributor/Wholesaler - Medicines and Medical Devices	5 500
Retailer - pharmacy dispensary, agricultural shops, vet clinics	4 500
Pharmacy - Within Group Practice	4 500
Institutional Pharmacy - Medicines and Medical Devices	4 800
Authorised Premises	
- Medium to Large Scale	500
- Small scale	250
Re-inspection	2 750
Licence variation	500
Voluntary consignment verification/inspection fee	1 500
Cosmetics - importer/distributor	5 000
Cosmetics - importer/retailer	2 500
Cosmetics - Cosmetics trader	500
Expedited	
Distributor / Wholesaler - Medicines and Medical Devices	11 000
Retailer - Pharmacy dispensary, agriculture shops, veterinary clinic	9 000
Pharmacy - within group practice	9 000
Institutional Pharmacy - Medicines and Devices	9 600

SCHEDULE 3

PERMIT FEES

Activity	Fee (BWP)
Application to import / export for all regulated products excluding Narcotics psychotropics & precursor chemicals	250
Application to import/export Narcotics psychotropics & precursor chemicals	500
Application to vary the import or export permit of Narcotics psychotropics & precursor chemicals	100
Importation fee for wholesale exempted products	1.25% of consignment value
Import Invoice fee for repeat wholesale exempted products without parallel dossier submission	1.5% of consignment value
Importation Invoice fee for all other products	0.8% of consignment value
Application for Transit Permit	250
Permit Variation for all (medicines and devices) except HFDs	100
Expedited	
Application to import / export for all regulated products excluding Narcotics psychotropics & precursor chemicals	500
Application to import/export Narcotics psychotropics & precursor chemicals	1 000
Application to vary the import or export permit of Narcotics psychotropics & precursor chemicals	200

SCHEDULE 4

4. REGISTRATION FEES

4.1. HUMAN MEDICINES (INTERNATIONAL APPLICANTS)

(New Chemical Entity)	**Fee (USD)**
Biologic & biosimilar	1 800
Small Molecules, including B-listed products	1 800
Vaccine	1 800
Expedited	
Biologic & biosimilar	3 600
Small Molecules, including B-listed products	3 600
Vaccine	3 600
(Generic)	
Small Molecules	1 260
Evaluation of additional submitted clinical data (pre-registration)	1 260
Line extension (New Chemical Entity and Generic)	1 260
Registration of an orphan medicine	1 260
Expedited	
Small Molecules	2 520
Evaluation of additional submitted clinical data (pre-registration)	2 520
Line extension (New Chemical Entity and Generic)	2 520
Registration of an orphan medicine	2 520
Renewals	
(New Chemical Entity)	
Biologic & biosimilar	900
Small Molecules, including B-listed products	900
Vaccine	900
(Generic)	
Small Molecules	630
Orphan medicine	630
Retentions	
Annual Retention Fee for All Products	150
Variations (NCE & Generic)	
- major	415
- minor	275
- notification	195

4.2. APPLICATION FOR REGISTRATION OF HUMAN MEDICINES – LOCAL APPLICANTS

Locally Manufactured Products	**Fee (BWP)**
Medicine partly manufactured in Botswana	12 000

Medicine fully manufactured in Botswana	10 000
Line extension (New Chemical Entity)	6 000
Line extension (Generics)	6 000
Expedited	
Medicine partly manufactured in Botswana	24 000
Medicine fully manufactured in Botswana	20 000
Renewals	
Medicine partly manufactured in Botswana	6 000
Medicine fully manufactured in Botswana	5 000
Retentions	
Annual Retention Fee for All Products	1 500
Application for Variation (NCE & Generic)	
- major	6 000
- minor	3 000
- notification	2 000
Exemptions	
Exemptions (Wholesale)	1.25 of consignment value or 8 500 whichever is greater
Repeat Wholesale exemption without proof of Application for registration	1.5% of consignment value + 10 000 whichever is greater
Exemptions (group hospital import)	350
Exemptions (prescription/patient-based)	Fee waived

4.3. APPLICATION FOR REGISTRATION OF MEDICAL DEVICES (MD) INCLUDING IN-VITRO DIAGNOSTICS (IVDs) - INTERNATIONAL APPLICANTS

New Applications (MD including IVDs)	**Fee (USD)**
Class A & notifiable	185
Class B	1 110
Class C&D	1 555
Expedited	
Class A & notifiable	370
Class B	2 220
Class C&D	3 110
Renewal	
Class A & notifiable	93
Class B	556
Class C&D	778
Retentions	
Annual retention fee for all products	1500
Variations	

- Major	225
- Minor	150
- Notification / notified variations	75

4.4. APPLICATION FOR REGISTRATION OF MEDICAL DEVICES (MD) INCLUDING IN-VITRO DIAGNOSTICS (IVDs) - LOCAL APPLICANTS

New Applications (MD including IVDs)	**Fee (BWP)**
Class A & notifiable fully manufactured in Botswana	1 500
Class A & notifiable partly manufactured in Botswana	1 875
Class B fully manufactured in Botswana	8 600
Class B partly manufactured in Botswana	12 800
Classes C&D fully manufactured in Botswana	10 300
Classes C&D partly manufactured in Botswana	15 400
Expedited	
Class A & notifiable fully manufactured in Botswana	3 000
Class A & notifiable partly manufactured in Botswana	3 750
Class B fully manufactured in Botswana	17 200
Class B partly manufactured in Botswana	25 600
Classes C&D fully manufactured in Botswana	20 600
Classes C&D partly manufactured in Botswana	30 800
Renewal	
Class A & notifiable fully manufactured in Botswana	750
Class A & notifiable partly manufactured in Botswana	938
Class B fully manufactured in Botswana	4 300
Class B partly manufactured in Botswana	6 400
Classes C&D fully manufactured in Botswana	5 150
Classes C&D partly manufactured in Botswana	7 700
Retentions	
Annual retention fee for all products	1 500
Variations	
- Major	3 000
- Minor	2 000
- Notification / notified variations	1 000
Exemptions	
MD including IVDs exemptions	500
Exemptions (prescription/patient-based) (Classes A & B)	Fee waived

4.5. APPLICATION FOR REGISTRATION OF VETERINARY MEDICINES (VMPs) - INTERNATIONAL APPLICANTS

Imported Fully Finished VMPs	**Fee (USD)**
Small-molecule medicines	1 125
Line extension	560
Vaccine/Biologicals	1 125
Complementary VMPs incl. premixes	560
Additional submitted data (pre-reg)	560
Orphan medicines	280
Expedited	
Small-molecule medicines	2 250
Line extension	1120
Vaccine/Biologicals	2 250
Complementary VMPs incl. remixes	1 120
Additional submitted data (pre-reg)	1 120
Orphan medicines	560
Renewals	
Small-molecule medicines	563
Line Extension	280
Vaccines/Biologicals	563
Complementary VMP including premixes	280
Additional submitted data (pre-reg)	280
Orphan medicines	140
Retentions	
Annual Retention Fee for all VMPs, excluding orphan medicines	150
Variation	
- major	370
- minor	280
- notification	190

4.6. APPLICATION FOR REGISTRATION OF VETERINARY MEDICINES (VMPs) - LOCAL APPLICANTS

Registration for imported fully finished VMPs	**Fee (BWP)**
Small-molecule medicines	15 200
Line extension	7 600
Vaccine/Biologicals	15 200
Complementary VMPs incl. premixes	7 600
Additional submitted data (pre-reg)	7 600
Orphan medicines	3 800
Expedited	
Small-molecule medicines	30 400

Line extension	15 200
Vaccine/Biologicals	30 400
Complementary VMPs incl. premixes	15 200
Additional submitted data (pre-reg)	15 200
Orphan medicines	7 600
Registration of partially Locally manufactured VMPs	
Small-molecule medicines	11 400
Line Extension	5 700
Vaccines/Biologicals	11 000
Complementary VMP incl premixes	5 700
Additional submitted data (pre-reg)	5 700
Orphan medicines	2 800
Expedited	
Small-molecule medicines	22 800
Line Extension	11 400
Vaccines/Biologicals	22 000
Complementary VMP incl premixes	11 400
Additional submitted data (pre-reg)	11 400
Orphan medicines	5 600
Registration of fully locally manufactured VMPs	
Small-molecule medicines	7 600
Line Extension	3 800
Vaccines/Biologicals	7 600
Complementary VMP incl Premixes	3 800
Additional submitted data (pre-reg)	3 800
Orphan medicines	1 900
Expedited	
Small-molecule medicines	15 200
Line Extension	7 600
Vaccines/Biologicals	15 200
Complementary VMP incl premixes	7 600
Additional submitted data (pre-reg)	7 600
Orphan medicines	3 800
Retention	
Annual Retention Fee for all VMPs excl orphan medicines	1 500
Annual Retention of orphan medicines	Fee waived
Renewal	
Renewal for Imported Fully Finished VMPs	
Small-molecule medicines	7 600
Line extension	3 800
Vaccine/Biologicals	7 600
Complementary VMPs incl. premixes	3 800
Additional submitted data (pre-reg)	3 800
Orphan medicines	1 900
Renewal of partially Locally manufactured VMPs	
Small molecule medicines	5 700
Line Extension	2 850
Vaccines/Biologicals	5 500

Complementary VMP incl premixes	2 850
Additional submitted data (pre-reg)	2 850
Orphan medicines	1 400
Renewal of fully locally manufactured VMPs	
Small-molecule medicines	3 800
Line Extension	1 900
Vaccines/Biologicals	3 800
Complementary VMP incl premixes	1 900
Additional submitted data (pre-reg)	1 900
Orphan medicines	950
Exemption from registration of VMPs	
Prescription/patients based	Nil
Hospital/Vet clinics	50
Research	150
Wholesale	3000
Application for Variation of all VMPs	
- Major	3 700
- Minor	2 800
- Notification	1 900

4.7. APPLICATION FOR REGISTRATION OF COMPLEMENTARY MEDICINES-INTERNATIONAL APPLICANT

Imported Fully Finished Complementary Medicine	**Fee (USD)**
Complementary medicines registration	585
A line extension of Complementary medicine	370
Expedited	
Complementary medicines registration	1170
Renewal	
Renewal of registration	293
Retention	
Annual fee/ retention fee	150
Variation	
Variation	185
Registrability	
Determination of Product Registrability	80

4,8. APPLICATION FOR REGISTRATION OF COMPLEMENTARY MEDICINES - LOCAL APPLICANT

Registration of Partially Locally Manufactured Complementary Medicine	**Fee (BWP)**
Complementary medicine partially manufactured in Botswana	6 000
Registration of Fully Locally Manufactured	
Full manufacturing of complementary medicines	4 000

Expedited	
Registration of partially manufactured complementary medicine in Botswana	12 000
Complementary medicine fully manufactured in Botswana	8 000
Retentions	
Annual fee/ retention fee	1 500
Renewal	
Registration of partially locally manufactured complementary medicine	3 000
Registration of fully locally manufactured	2 000
Variations	
Variations	2 500
Registrability	
Determination of Product Registrability	400

4.9. APPLICATION FOR REGISTRATION OF COSMETICS - INTERNATIONAL APPLICANTS

Notification/listing of Imported cosmetics	**Fee (USD)**
Cosmetics partially manufactured in Botswana	90
Registration of imported cosmetics	
Imported Cosmetics registration	300
A line extension of Cosmetics	225
Renewal of Registration	
Renewal of imported cosmetics registration	150
Retention	
Retention of imported cosmetics	22
Variations	
Variations	40
Exemption	
Exemption from registration	225

4.10. APPLICATION FOR REGISTRATION OF COSMETICS - LOCAL APPLICANTS

Notification/listing of Partially Locally Manufactured	**Fee (BWP)**
Cosmetics partially manufactured in Botswana	1200
Notification/listing of Fully Locally Manufactured	
Full manufacturing of cosmetics	600
Registration or Partially Locally Manufactured	
Registration of partially locally manufactured complementary medicine	4 000
Registration of fully locally manufactured	2 000
Renewal of Registration	
Renewal of partially locally manufactured cosmetics	2 000
Renewal of fully locally manufactured cosmetics	1 000
Retention	
Retention of partially locally manufactured cosmetics	300
Retention of fully locally manufactured cosmetics	200

Variation	
Variation	500
Exemption	
Exemption from registration	400

4.8.

SCHEDULE 5

APPLICATION TO CONDUCT CLINICAL TRIALS

Foreign Sponsor	**Fee (USD)**
Phase 1 study	3 700
Phase 2 study	3 000
Phase 3/4 study	2 500
Sub-study	1 000
Bioequivalence/Bioavailability	1 000
Amendment Application	
Amendment	200
By Local Sponsor	**Fee (BWP)**
Clinical trial	22 500
Sub-study	11 250
Bioequivalence/Bioavailability study	7 500
Amendment Application	
Local sponsor	**1 000**

SCHEDULE 6

APPLICATION FOR APPROVAL OF ADVERTISEMENT/PROMOTIONAL MATERIAL

International Applicant	**Fee (USD)**
Print/ electronic media	125
Local Applicant	**Fee (BWP)**
Print/ electronic media	1 250

SCHEDULE 7

OTHER REGULATORY FEES

Re-issue of certificates	100
Certificate (all products)	300
Variations (penalty fee)	5 000
Late submission of applications, including renewals retentions (penalty fee)	20% of the applicable process fee