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)

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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

Citation and commencement

1. (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.

Interpretation

2. 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 6(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;

"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;

"verification pathway" means a regulatory pathway relying substantially on prior approval by stringent regulatory authorities;

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

Application

3. (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, export and other activities;

(d) inspection and audit 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.

PART II — GENERAL PROVISIONS ON FEES

Fees payable

4. (1) The fees set out in Schedules 1 to 12 are payable for the applications, services, licences, permits, certificates and other matters specified therein.

(2) Fees shall be charged based on—

(a) the applicant's status as local or international;

(b) the regulatory pathway applicable;

(c) the risk classification of the product or activity;

(d) whether the product is locally manufactured;

(e) whether expedited service is requested; and

(f) such other factors as may be relevant.

(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.

Payment methods

5. (1) Fees and administrative penalties shall be paid by—

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

(b) bank-guaranteed cheque;

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

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

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

(2) Cash payments shall only be accepted at the Authority's offices.

(3) 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.

(4) Where payment is made from outside Botswana—

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

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

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

Currency provisions

6. (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.

Fee exemptions and reductions

7. (1) The Chief Executive Officer may, in consultation with the Board, exempt or reduce fees where—

(a) the application relates to a product designated as essential for public health emergencies under section 38 of the Act;

(b) the application supports Government health programmes or citizen economic empowerment;

(c) exceptional circumstances exist that warrant fee relief;

(d) the application is for research or innovation aligned with national health priorities; or

(e) the full fee would unduly hinder access to essential medicines.

(2) The following standard reductions shall apply—

Category	Reduction
Locally manufactured products	As specified in Schedules
Orphan medical products — international applicants	50%
Orphan medical products — local applicants	100% (fee waived)
Neglected tropical diseases products	Up to 75%
Paediatric formulations	30%
Small-scale local applicants	25%
WHO Prequalified products	25%
Products for government procurement	20%
Combination products addressing multiple conditions	15% per additional indication

(3) An application for fee reduction shall—

(a) be made in writing before or together with the application;

(b) include supporting documentation;

(c) state the grounds for reduction; and

(d) be determined within fourteen working days.

(4) The Authority shall publish guidelines on fee exemptions and reductions.

(5) The Authority shall report annually on fee exemptions and reductions granted.

Refund policy

8. (1) Fees paid are generally non-refundable.

(2) A refund may be granted where—

(a) an application is withdrawn in writing before evaluation commences;

(b) a fee has been paid in error or in excess; or

(c) the Authority is unable to provide the service for which the fee was paid.

(3) Where a refund is approved—

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

(b) an administrative charge of twenty per cent shall be retained for applications withdrawn after validation but before evaluation; and

(c) the full amount, less bank charges, shall be refunded for payments made in error.

(4) No refund shall be made where—

(a) an application is refused after evaluation;

(b) an application is abandoned by the applicant after evaluation commences;

(c) evaluation has been substantially completed; or

(d) the refund request is made more than twelve months after payment.

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

Annual review mechanism

9. (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 public 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.

PART III — PRODUCT REGISTRATION FEES

Human medicines registration fees

10. (1) Fees for registration of human medicines are set out in Schedule 1.

(2) Registration pathways and associated fee tiers are—

(a) **Full Evaluation Pathway**: for new chemical entities, new biological entities, new fixed-dose combinations, and products without prior approval by a recognised regulatory authority;

(b) **Abridged Evaluation Pathway**: for products approved by a stringent regulatory authority or WHO Prequalified;

(c) **Verification Pathway**: for products approved by two or more stringent regulatory authorities with an established safety record; and

(d) **Generic Product Pathway**: for generic medicines with bioequivalence data.

(3) Additional fees apply for—

(a) expedited evaluation;

(b) multiple strengths or pack sizes, per additional presentation;

(c) line extensions;

(d) biological or biosimilar products; and

(e) complex formulations.

(4) Reduced fees apply for—

(a) products manufactured locally, whether partially or fully;

(b) essential medicines on the national list;

(c) orphan medical products; and

(d) paediatric formulations.

Veterinary medicines registration fees

11. (1) Fees for registration of veterinary medicines are set out in Schedule 2.

(2) The fee structure mirrors that for human medicines, with adjustments for—

(a) vaccines and biologicals;

(b) antimicrobials subject to stewardship programmes;

(c) products for food-producing animals requiring residue data;

(d) ectoparasiticides and endoparasiticides; and

(e) medicated feed premixes.

(3) Specific provisions apply for products addressing—

(a) livestock diseases of national importance;

(b) wildlife conservation; and

(c) aquaculture.

Medical devices registration fees

12. (1) Fees for registration of medical devices are set out in Schedule 3.

(2) Fees are differentiated by risk classification—

(a) Class A (low risk): notification pathway fees;

(b) Class B (low-moderate risk): standard evaluation fees;

(c) Class C (moderate-high risk): enhanced evaluation fees; and

(d) Class D (high risk): full evaluation fees.

(3) Special fee provisions apply for—

(a) software as a medical device;

(b) devices enabled by artificial intelligence or machine learning;

(c) combination products;

(d) custom-made devices; and

(e) refurbished devices.

(4) Grouped application discounts apply where—

(a) multiple variants of the same device family, system or group are submitted;

(b) the devices are manufactured at the same site; and

(c) the devices share the same intended use and risk classification.

In-vitro diagnostics registration fees

13. (1) Fees for registration of in-vitro diagnostic medical devices are set out in Schedule 4.

(2) Fees are differentiated by risk classification—

(a) Class A (low individual risk and low public health risk): notification fees;

(b) Class B (moderate individual risk and low public health risk): standard evaluation fees;

(c) Class C (high individual risk and moderate public health risk): enhanced evaluation fees; and

(d) Class D (high individual risk and high public health risk): comprehensive evaluation fees.

(3) Special fee provisions apply for—

(a) diagnostics for infectious diseases;

(b) blood screening tests;

(c) self-testing devices;

(d) companion diagnostics; and

(e) multiplex assays.

Blood and blood products fees

14. (1) Fees for blood and blood products are set out in Schedule 5.

(2) Fee categories include—

(a) plasma-derived medicinal products registration;

(b) recombinant blood products registration;

(c) blood establishment licensing;

(d) batch release certification; and

(e) plasma master file evaluation.

(3) Reduced fees apply for public sector blood establishments.

Complementary medicines registration fees

15. (1) Fees for complementary medicines are set out in Schedule 6.

(2) Simplified fee structures apply for—

(a) products with a long history of traditional use;

(b) products on approved reference lists;

(c) homeopathic preparations; and

(d) nutritional supplements meeting notification criteria.

Cosmetics notification and registration fees

16. (1) Fees for cosmetics are set out in Schedule 7.

(2) Fee levels differentiate between—

(a) notification for general-use cosmetics;

(b) registration for special-use cosmetics; and

(c) products making specific claims.

(3) Reduced fees apply for—

(a) local manufacturers;

(b) small-scale producers; and

(c) traditional cosmetic preparations.

Traditional medicines registration fees

17. (1) Fees for traditional medicines are set out in Schedule 8.

(2) Simplified registration pathways and reduced fees support—

(a) indigenous knowledge holders;

(b) traditional health practitioners;

(c) local community-based production; and

(d) products with established traditional use.

(3) Technical assistance may be provided for first-time traditional medicine applicants at no additional cost.

Orphan medical products fee provisions

18. (1) In accordance with section 44 of the Act, special fee provisions apply to orphan medical products.

(2) For international applicants—

(a) registration fees are reduced by fifty per cent;

(b) annual retention fees are reduced by fifty per cent; and

(c) variation fees follow the standard rates.

(3) For local applicants—

(a) registration fees are waived;

(b) annual retention fees are waived; and

(c) variation fees are reduced by fifty per cent.

(4) To qualify for orphan medical product fee benefits, the applicant shall—

(a) apply for and receive orphan medical product designation before or together with the registration application;

(b) demonstrate that the product addresses a rare disease afflicting not more than five per cent of the population of Botswana, or as may be prescribed; and

(c) demonstrate that no satisfactory alternative is available.

PART IV — LICENSING FEES

Manufacturing facility licensing fees

19. (1) Licensing fees for manufacturing facilities are set out in Schedule 9.

(2) Fees are differentiated by—

(a) the type of products manufactured;

(b) the scale of operations;

(c) whether manufacturing is sterile or non-sterile;

(d) whether manufacturing is biological or conventional; and

(e) the number of manufacturing lines or blocks.

(3) Incentive fees apply for—

(a) first-time local manufacturers;

(b) manufacturers investing in active pharmaceutical ingredient production;

(c) manufacturers addressing essential medicines gaps; and

(d) manufacturers achieving international certifications.

(4) Combined facility discounts apply where multiple activities are licensed at one site.

Import and export licensing fees

20. (1) Import and export licensing fees are set out in Schedule 10.

(2) Fees are differentiated by—

(a) entity size and turnover;

(b) the categories of product imported or exported;

(c) the number of registered products; and

(d) the compliance history of the entity.

(3) Reduced fees apply for—

(a) entities importing exclusively for Government programmes;

(b) entities supporting local manufacturing through raw material imports; and

(c) entities with excellent compliance records.

Wholesale and distribution licensing fees

21. (1) Wholesale and distribution licensing fees are set out in Schedule 10.

(2) Fees are differentiated by—

(a) geographical coverage;

(b) the categories of product distributed;

(c) the number of distribution points; and

(d) cold chain capability.

Retail and dispensing licensing fees

22. (1) Retail and dispensing licensing fees are set out in Schedule 10.

(2) Categories include—

(a) community pharmacies;

(b) hospital pharmacies;

(c) veterinary pharmacies;

(d) dispensaries;

(e) authorised health facility dispensaries; and

(f) group practice pharmacies.

(3) Reduced fees apply for—

(a) pharmacies in underserved areas;

(b) public sector facilities; and

(c) first-time licensees.

Blood establishment licensing fees

23. (1) Blood establishment licensing fees are set out in Schedule 5.

(2) Categories include—

(a) national blood service;

(b) regional blood centres;

(c) hospital blood banks;

(d) plasma collection centres; and

(e) cord blood banks.

(3) Public sector blood establishments receive reduced fees.

Special purpose licensing fees

24. (1) Special purpose licensing fees are set out in Schedule 10.

(2) Categories include—

(a) clinical trial supply licences;

(b) online sales licences;

(c) bonded warehouse licences;

(d) repackaging and relabelling licences; and

(e) contract manufacturing licences.

PART V — PERMIT AND SERVICE FEES

Import and export permit fees

25. (1) Import and export permit fees are set out in Schedule 11.

(2) Standard permit fees apply per consignment.

(3) Expedited permit fees are available for urgent requirements.

(4) Reduced fees apply for—

(a) essential medicines imports;

(b) emergency imports during shortages;

(c) samples for registration purposes; and

(d) research materials.

Transit permit fees

26. (1) Transit permit fees are set out in Schedule 11.

(2) Fees are based on—

(a) product category;

(b) quantity; and

(c) transit duration.

Clinical trial authorisation fees

27. (1) Clinical trial authorisation fees are set out in Schedule 11.

(2) Fees are differentiated by—

(a) trial phase;

(b) sponsor type;

(c) number of sites; and

(d) complexity of protocol.

(3) Reduced fees apply for—

(a) locally-sponsored trials;

(b) trials addressing local health priorities;

(c) academic and investigator-initiated trials; and

(d) trials in collaboration with Government.

(4) Amendment fees are lower than initial application fees.

Advertising approval fees

28. (1) Advertising approval fees are set out in Schedule 11.

(2) Fees are differentiated by—

(a) media type;

(b) the intended audience; and

(c) campaign duration.

Laboratory services fees

29. (1) Laboratory testing fees are set out in Schedule 12.

(2) Fees are based on—

(a) test complexity;

(b) sample type; and

(c) urgency of results.

(3) Reduced fees apply for—

(a) regulatory testing for post-market surveillance purposes;

(b) testing for local manufacturers;

(c) testing for the public sector; and

(d) academic research.

Certificate and document fees

30. (1) Certificate and document fees are set out in Schedule 11.

(2) Categories include—

(a) Certificate of Pharmaceutical Product;

(b) Free Sale Certificate;

(c) Good Manufacturing Practice Certificate;

(d) Letter of Authorisation;

(e) certified copies of registration certificates;

(f) export certificates; and

(g) letters of confirmation.

PART VI — INSPECTION FEES

Good manufacturing practice inspection fees

31. (1) Good manufacturing practice inspection fees for manufacturing sites are set out in Schedule 12.

(2) Fees for inspection of foreign sites are differentiated by location—

(a) Southern African Development Community region;

(b) rest of Africa;

(c) Asia;

(d) Europe and the Americas; and

(e) rest of world.

(3) Fees include—

(a) inspector time;

(b) travel and accommodation for foreign site inspections;

(c) report preparation; and

(d) follow-up assessment.

(4) Desk review fees apply where on-site inspection is not required.

(5) Additional fees apply for—

(a) additional manufacturing blocks or lines;

(b) re-inspection following significant non-compliance;

(c) expedited inspection scheduling; and

(d) complex facilities, including sterile and biological manufacturing.

(6) Reduced fees apply where—

(a) the site holds a current certification from a stringent regulatory authority;

(b) a joint inspection with another regulatory authority is conducted; or

(c) a reliance pathway applies.

Good distribution practice inspection fees

32. (1) Good distribution practice inspection fees are set out in Schedule 12.

(2) Fees are differentiated by—

(a) entity type;

(b) scale of operations;

(c) the categories of product handled; and

(d) cold chain requirements.

(3) Follow-up inspection fees apply for verification of corrective actions.

Blood establishment inspection fees

33. (1) Blood establishment inspection fees are set out in Schedule 5.

(2) Fees reflect the complexity and scope of the blood establishment's operations.

(3) Public sector facilities receive reduced inspection fees.

Clinical trial site inspection fees

34. (1) Clinical trial site inspection fees are set out in Schedule 11.

(2) Good clinical practice inspection fees apply to—

(a) pre-approval inspections;

(b) routine inspections;

(c) for-cause inspections; and

(d) sponsor audits.

Special inspection fees

35. (1) Special inspection fees apply to—

(a) for-cause inspections triggered by complaints or safety signals;

(b) emergency inspections;

(c) joint inspections with other authorities; and

(d) inspections requested by the entity.

(2) For-cause inspection fees shall be borne by the inspected entity where significant non-compliance is confirmed.

PART VII — MAINTENANCE AND VARIATION FEES

Annual retention fees

36. (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.

(5) Retention fees contribute to ongoing regulatory oversight including—

(a) pharmacovigilance monitoring;

(b) post-market surveillance;

(c) maintenance of registers; and

(d) periodic benefit-risk review.

Variation fees

37. (1) Variation fees are set out in the respective Schedules.

(2) Fees are differentiated by variation type—

(a) **major variations**: highest fees for changes with potential significant impact on quality, safety or efficacy;

(b) **minor variations**: moderate fees for changes with limited impact; and

(c) **notifications**: lowest fees for administrative changes.

(3) Grouped variation fees apply where multiple related variations are submitted together.

(4) Urgent safety variation fees are reduced for variations protecting public health.

Renewal fees

38. (1) Renewal fees for registrations and licences are set out in the respective Schedules.

(2) Renewal fees are generally set at sixty per cent of the initial registration or licensing fee.

(3) Expedited renewal fees apply where late submission necessitates priority processing.

PART VIII — LEVIES

Regulatory levy

39. (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—

(a) products imported for Government programmes;

(b) humanitarian donations; and

(c) products imported for re-export.

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

Pharmacovigilance levy

40. (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 levy is calculated as—

(a) P500 per registered product for international marketing authorisation holders; and

(b) P250 per registered product for local marketing authorisation holders.

(3) Caps apply as follows—

(a) a maximum of P50,000 per marketing authorisation holder for international holders; and

(b) a maximum of P25,000 per marketing authorisation holder for local holders.

(4) The levy is payable together with annual retention fees.

Post-market surveillance levy

41. (1) A post-market surveillance levy shall be payable to fund market surveillance activities under section 74 of the Act.

(2) The levy shall be incorporated into annual retention fees.

(3) Enhanced surveillance fees may apply for—

(a) products subject to risk evaluation and mitigation strategies;

(b) products with safety signals under investigation; and

(c) products requiring enhanced monitoring.

PART IX — PENALTIES AND SANCTIONS

Late payment penalties

42. (1) Late payment penalties apply to overdue fees as follows—

Days Overdue	Penalty
1–30 days	10% of outstanding amount

31–60 days	20% of outstanding amount
61–90 days	30% of outstanding amount
Over 90 days	Suspension of registration or ~~licence~~license, plus 30% penalty

(2) Interest at the rate of two per cent per month shall compound on unpaid amounts after sixty days.

(3) The Authority may waive penalties where—

(a) late payment results from a demonstrable error by the Authority;

(b) exceptional circumstances exist and are documented; or

(c) payment arrangements have been agreed in writing.

Administrative penalties

43. (1) The Authority may, in accordance with section 6(i) of the Act, impose administrative penalties for regulatory violations without court proceedings.

(2) The administrative penalty framework shall be implemented in accordance with guidelines issued by the Authority.

(3) Factors in determining administrative penalty amounts include—

(a) severity of the violation;

(b) risk to public health;

(c) whether the violation was wilful or negligent;

(d) compliance history;

(e) cooperation with the Authority;

(f) remedial actions taken; and

(g) economic benefit derived from the violation.

(h) Administrative penalties so imposed shall be collected in accordance with set guidelines on imposition and collection of fines.

(4) Administrative penalties do not preclude—

(a) prosecution for criminal offences under the Act;

(b) suspension or cancellation of registration or licence;

(c) product recall under section 75 of the Act; or

(d) other regulatory action.

Compound penalties

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

Offence	Maximum Compound Amount
Advertising without approval	P500,000
Minor labelling violations	P250,000
Late notification of changes	P100,000
Minor record-keeping violations	P100,000
Late renewal applications	P50,000
First-time import documentation violations	P250,000
Minor premises compliance issues	P150,000
Failure to submit required reports	P100,000

(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 is as follows—

(a) the person must admit the offence in writing;

(b) the compound offer must be made before the commencement of court proceedings;

(c) payment must be made within thirty days of the offer; and

(d) failure to pay within the specified period shall result in prosecution.

Risk-based penalty framework

45. (1) Penalties shall be determined using a risk-based approach, and may consider the following factors—

Factor	Weight	High (3)	Medium (2)	Low (1)
Patient harm potential	30%	Actual or likely harm	Possible harm	Unlikely harm
Population exposure	20%	Widespread	Moderate	Limited
Intentionality	20%	Deliberate	Negligent	Inadvertent
Duration of violation	15%	Extended	Moderate	Brief

Detection difficulty	15%	Concealed	Not reported	Self-reported

(2) Penalty multipliers based on total risk score are as follows—

(a) high risk (score 12–15): maximum penalty range;

(b) medium risk (score 8–11): mid-range penalty; and

(c) low risk (score 5–7): minimum penalty range.

(3) Mitigating factors that may reduce penalties include—

(a) voluntary disclosure;

(b) immediate corrective action;

(c) cooperation with investigation;

(d) no prior violations;

(e) good faith compliance efforts; and

(f) documented financial hardship.

(4) Aggravating factors that may increase penalties include—

(a) repeat violations;

(b) obstruction of investigation;

(c) concealment of evidence;

(d) actual patient harm;

(e) economic exploitation; and

(f) vulnerability of the affected population.

PART X — TRANSITIONAL AND FINAL PROVISIONS

Transitional provisions

46. (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.

Phased implementation

47. (1) The following phased implementation applies—

Fee Category	Implementation Date
Product registration fees	1 April 2026
Licensing fees	1 April 2026
Permit fees	1 April 2026
Inspection fees	1 July 2026
Levies	1 October 2026
Administrative penalties	1 January 2027

(2) The Authority shall publish implementation guidance at least ninety days before each implementation date.

Repeal

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

SCHEDULES

SCHEDULE 1

HUMAN MEDICINES REGISTRATION FEES

Table 1.1: International Applicants — New Applications

Product Type / Pathway	Standard Fee (USD)	Expedited Fee (USD)
Full Evaluation Pathway		
New Chemical Entity	8,000	16,000
New Biological Entity	10,000	20,000
New Fixed-Dose Combination	6,000	12,000
Abridged Pathway		
SRA-approved product	4,000	8,000
WHO Prequalified product	3,000	6,000
Verification Pathway		
Multiple SRA approvals	2,500	5,000
Generic Products		
With bioequivalence study	3,500	7,000
With biowaiver	2,500	5,000
Line Extension	2,000	4,000
Additional Strength/Pack	500	1,000

Table 1.2: International Applicants — Maintenance

Fee Type	Fee (USD)
Annual Retention	800
Major Variation	2,000
Minor Variation	800
Notification	200
Renewal (5-year)	4,000

Table 1.3: Local Applicants — New Applications

Product Type / Manufacturing	Fee (BWP)	Expedited (BWP)
Imported Products		
New product	45,000	90,000
Generic product	30,000	60,000
Line extension	15,000	30,000
Partially Locally Manufactured		

New product	30,000	60,000
Generic product	20,000	40,000
Line extension	10,000	20,000
Fully Locally Manufactured		
New product	20,000	40,000
Generic product	12,000	24,000
Line extension	6,000	12,000

Table 1.4: Local Applicants — Maintenance

Fee Type	Fee (BWP)
Annual Retention — Imported	8,000
Annual Retention — Partial local manufacture	5,000
Annual Retention — Full local manufacture	3,000
Major Variation	15,000
Minor Variation	8,000
Notification	2,000

SCHEDULE 2

VETERINARY MEDICINES REGISTRATION FEES

Table 2.1: International Applicants

Product Type	Standard Fee (USD)	Expedited Fee (USD)
New veterinary medicine	6,000	12,000
Generic veterinary medicine	3,000	6,000
Veterinary vaccine/biological	8,000	16,000
Medicated premix	2,500	5,000
Line extension	1,500	3,000

Table 2.2: Maintenance Fees

Fee Type	International (USD)	Local (BWP)
Annual Retention	600	4,000
Major Variation	1,500	10,000
Minor Variation	600	5,000
Notification	150	1,500

SCHEDULE 3

MEDICAL DEVICES REGISTRATION FEES

Table 3.1: International Applicants by Risk Class

Device Class	Standard Fee (USD)	Expedited Fee (USD)
Class A (Low Risk)	500	1,000
Class B (Low-Moderate)	1,500	3,000
Class C (Moderate-High)	3,000	6,000
Class D (High Risk)	5,000	10,000
AIMD/Implantable	6,000	12,000
Software as Medical Device	2,000	4,000

Table 3.2: Grouped Application Discounts

Number of Variants	Discount
2–5 variants	20%
6–10 variants	30%
11–20 variants	40%
Over 20 variants	50%

Table 3.3: Maintenance Fees

Fee Type	International (USD)	Local (BWP)
Annual Retention — Class A	100	800
Annual Retention — Class B	250	2,000
Annual Retention — Class C	400	3,500
Annual Retention — Class D	600	5,000
Significant Variation	1,500	12,000
Minor Variation	500	4,000
Notification	100	800

SCHEDULE 4

IN-VITRO DIAGNOSTICS REGISTRATION FEES

Table 4.1: By Risk Class

IVD Class	Standard Fee (USD)	Expedited Fee (USD)
Class A (Low)	400	800
Class B (Moderate)	1,200	2,400
Class C (High)	2,500	5,000
Class D (Highest)	4,000	8,000
Self-testing IVD	1,500	3,000
Blood screening IVD	3,500	7,000
Companion diagnostic	3,000	6,000

SCHEDULE 5

BLOOD AND BLOOD PRODUCTS FEES

Table 5.1: Blood Establishment Licensing

Establishment Type	Application Fee (BWP)	Annual Fee (BWP)
National Blood Service	50,000	25,000
Regional Blood Centre	30,000	15,000
Hospital Blood Bank	15,000	8,000
Plasma Collection Centre	25,000	12,000

Table 5.2: Blood Product Registration (International)

Product Type	Fee (USD)
Plasma-derived medicinal product	6,000
Recombinant blood product	5,000
Plasma master file evaluation	8,000
Batch release certificate	500

Table 5.3: Inspection Fees

Inspection Type	Fee (BWP)
Pre-licensing inspection	15,000
Routine inspection	10,000
For-cause inspection	20,000

SCHEDULE 6

COMPLEMENTARY MEDICINES FEES

Table 6.1: Registration Fees

Applicant Type	Registration Fee	Annual Retention
International	USD 600	USD 150
Local — Imported	BWP 8,000	BWP 1,500
Local — Partial manufacture	BWP 6,000	BWP 1,200
Local — Full manufacture	BWP 4,000	BWP 800

SCHEDULE 7

COSMETICS FEES

Table 7.1: Notification and Registration

Category	International (USD)	Local (BWP)
Notification — General use	100	600
Registration — Special use	300	4,000
Line extension	75	500
Annual retention	25	200
Variation	50	500

SCHEDULE 8

TRADITIONAL MEDICINES FEES

Table 8.1: Registration Fees

Category	Fee (BWP)
Traditional medicine — Individual practitioner	1,000
Traditional medicine — Small enterprise	3,000
Traditional medicine — Commercial scale	8,000
Annual retention	500
Variation	1,000

SCHEDULE 9

MANUFACTURING LICENSING FEES

Table 9.1: Medicines Manufacturing

Facility Type	Application (BWP)	Annual (BWP)
Large scale — Sterile	100,000	50,000
Large scale — Non-sterile	75,000	35,000
Medium scale	50,000	25,000
Small scale	25,000	12,000
Repackaging only	15,000	8,000

Table 9.2: Medical Devices Manufacturing

Facility Type	Application (BWP)	Annual (BWP)
Class C/D devices	80,000	40,000
Class A/B devices	50,000	25,000
Class A devices only	25,000	12,000

Table 9.3: Cosmetics Manufacturing

Scale	Application (BWP)	Annual (BWP)
Large	30,000	15,000
Medium	20,000	10,000
Small	10,000	5,000
Cottage/artisanal	3,000	1,500

SCHEDULE 10

DISTRIBUTION AND RETAIL LICENSING FEES

Table 10.1: Import/Export Licensing

Category	Application (BWP)	Annual (BWP)
Import licence — Large	25,000	12,000
Import licence — Medium	15,000	8,000
Import licence — Small	8,000	4,000
Export licence	15,000	8,000

Table 10.2: Wholesale and Distribution

Category	Application (BWP)	Annual (BWP)
National wholesaler	30,000	15,000
Regional wholesaler	20,000	10,000
Local distributor	10,000	5,000
Bonded warehouse	15,000	8,000

Table 10.3: Retail Licensing

Category	Application (BWP)	Annual (BWP)
Community pharmacy	8,000	4,000
Hospital pharmacy	6,000	3,000
Veterinary pharmacy	6,000	3,000
Dispensary	4,000	2,000
Authorised premises	3,000	1,500
Online pharmacy (additional)	10,000	5,000

SCHEDULE 11

PERMIT AND SERVICE FEES

Table 11.1: Import/Export Permits

Permit Type	Standard (BWP)	Expedited (BWP)
Import permit — Medicines	200	400
Import permit — Devices	150	300
Import permit — Cosmetics	100	200
Import permit — Controlled substances	500	1,000
Export permit	150	300
Transit permit	250	500
Samples import permit	100	200
Permit variation — Medicines	100	200
Permit variation — Devices	100	250
Permit variation — Controlled substances	250	500

Table 11.2: Clinical Trial Fees

Category	International (USD)	Local (BWP)
Phase I trial	4,000	25,000
Phase II trial	3,500	22,000
Phase III trial	3,000	20,000
Phase IV trial	2,000	15,000
Bioequivalence study	1,500	10,000
Protocol amendment	500	3,000
Annual report review	200	1,500
Site inspection	1,500	10,000

Table 11.3: Advertising Approval

Media Type	International (USD)	Local (BWP)
Print media	150	1,500
Broadcast media	200	2,000
Digital/online	150	1,500
Point of sale	100	1,000
Professional materials	100	1,000

Table 11.4: Certificates and Documents

Document	Fee (BWP)
Certificate of Pharmaceutical Product	500
Free Sale Certificate	400
GMP Certificate	500
Letter of Authorisation	300
Certified copy of registration certificate	150
Letter of confirmation	200
Re-issue of lost certificate	200
Name search/reservation	100

SCHEDULE 12

INSPECTION AND LABORATORY FEES

Table 12.1: GMP Inspection — Foreign Sites

Location	Standard (USD)	Expedited (USD)
SADC	4,000	8,000
Rest of Africa	5,500	11,000
Asia	7,000	14,000
Europe/Americas	7,500	15,000
Rest of World	8,000	16,000
Desk review only	3,500	—

Additional charges:

Additional manufacturing block: USD 1,200

Re-inspection (non-compliance): 50% of inspection fee

Expedited scheduling: 50% surcharge

Table 12.2: GMP Inspection — Local Sites

Facility Type	Fee (BWP)
Large manufacturer	25,000
Medium manufacturer	15,000
Small manufacturer	8,000
Follow-up inspection	5,000

Table 12.3: GDP Inspection

Entity Type	Fee (BWP)
National wholesaler	10,000
Regional distributor	6,000
Retail pharmacy	3,000
Follow-up inspection	2,000

Table 12.4: Laboratory Testing

Test Category	Fee Range (BWP)
Full pharmacopoeial analysis	8,000–25,000
Dissolution testing	3,000–6,000

Content uniformity	2,500–4,500
Sterility testing	4,000–8,000
Microbial limits	2,500–5,000
Identity testing	1,500–3,000
Basic quality screen	2,000–4,000

Note: The exact fee depends on product complexity and the number of tests required.

Made this _____ day of _____, 2026

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Minister of Health