NCCMRP - MOZAMBIQUE

National Controlled Cannabinoid Medical Research Pilot Programme

Government Approval, Scientific Research and Compliance Programme

DOCUMENT STATUS: FORMAL SUBMISSION DRAFT - SUBJECT TO MOZAMBICAN LEGAL OPINION AND GOVERNMENT APPROVAL

Prepared for pre-application engagement with the Council of Ministers, the authority responsible for Health, GCPCD, ANARME, INS, the authority responsible for Agriculture, Interior, Environment, Customs and the relevant provincial and district authorities.

Legal review date: 29 July 2026 | Proposed programme term: 36 months from the effective date of the final project authorisation.

Proposed sponsor: [INSERT MOZAMBICAN LEGAL ENTITY] | Public institutional host: [TO BE DESIGNATED] | Proposed site: [SUBJECT TO LEGAL AND ENVIRONMENTAL CLEARANCE]

Document Control and Legal Status

Field	Approved drafting position
Document purpose	Government pre-application and approval framework
Controlled activity status	No seed, plant, extract or cannabinoid product may be possessed until all conditions precedent are satisfied
Commercial status	Strictly non-commercial; no sale, supply, off-take, contract farming, advertising or patient access
Legal reliance	Formal Mozambican legal opinion and written government approvals are mandatory
Version	Approval Framework v1.0 - 29 July 2026

LEGAL LIMITATION: This programme is designed to obtain lawful authority; it does not itself grant authority. Government approval, publication of the enabling instrument where required, and an effective project-specific licence are conditions precedent to every controlled activity.

Decision Requested from Government

1. Designate a lead government authority and establish an interministerial steering committee for the proposed medical/scientific cannabis pilot.
2. Direct the Ministry responsible for Justice and the Attorney-General's Office to confirm the lawful form and authority for the enabling instrument.
3. Approve preparation of a narrow Council of Ministers decree or, if legally required, submit the necessary amendment or bill to the Assembly of the Republic.
4. Authorise Phase 0 regulatory, legal, site-screening and protocol-development activities only; no controlled plant activity is requested under Phase 0.
5. Following adoption of the enabling framework, invite a project-specific application from a recognised Mozambican public research institution.

Executive Approval Summary

The proposed programme is a non-commercial, time-limited and traceable medical/scientific research initiative for the controlled characterisation of authorised Cannabis sativa genetic material and, only after separate approvals, the development and evaluation of standardised cannabinoid investigational products. It is not an industrial-hemp business, an agricultural commercialisation project or a patient-access programme.

Article 34 of Law No. 3/97 criminalises unauthorised cultivation. The phrase 'not authorised' indicates that authorised activity is legally contemplated, but does not create a self-executing private licence. No published Mozambican industrial-hemp threshold or medical-cannabis cultivation procedure was identified in the public materials reviewed. The programme therefore makes the enabling legal instrument and project-specific authorisation its first substantive outputs.

APPROVAL PRINCIPLE: One controlled act, one express permission. Cultivation approval will not be treated as approval for transport, extraction, manufacture, human administration, sale, import or export.

Gate	Approval outcome	Controlled activity permitted	No-go consequence
0	Government accepts pre-application process	None	Project remains desk-based
1	Enabling legal instrument published	None until licence	No seed or plant acquisition
2	Project licence and facility readiness certificate effective	Only acts expressly listed	No planting or possession
3	Agricultural, ABS, land and environmental approvals effective	Authorised research cultivation	Site cannot operate
4	ANARME pharmaceutical approvals	Authorised development/manufacture	No extraction or investigational product
5	Ethics, INS and clinical-trial approvals	Approved human trial only	No recruitment or administration
6	AIM and separate commercial legal basis	Approved market activity	No sale or routine supply

1. Legal and Treaty Foundation

1.1 Controlled-plant law

Law No. 3/97 must be treated as the controlling statute unless Mozambican counsel identifies a later instrument that changes the analysis. Article 34 prohibits cultivation of Cannabis sativa by a person who is not authorised. Articles 4 and 34 indicate the possibility of authorised activity, while leaving the authority, conditions and procedure to regulation. The pilot must not infer a licence from silence or from a government partnership.

No foreign hemp threshold shall be imported into the Mozambican programme. All cannabis plant material, CBD-rich material, THC-containing material, extracts, concentrates, reference samples and research waste will be treated as controlled until a written Mozambican classification states otherwise.

1.2 GCPCD and government coordination

Decree No. 28/2023 places GCPCD under the Council of Ministers and gives it a national coordination role across health, police, customs, agriculture, justice and other sectors. The decree also tasks the relevant service with leading establishment of a system for managing

narcotic and psychotropic substances. GCPCD is therefore an essential coordinating participant, but its organic statute should not be mistaken for a cultivation licence.

1.3 International control obligations

Mozambique is party to the Single Convention on Narcotic Drugs as amended. If cannabis is cultivated for the production of cannabis, resin or extracts for medical/scientific purposes, the national framework should apply the control functions required by Articles 23 and 28. The enabling instrument should designate the competent national agency, licensed areas and cultivators; control quantities; provide for state control or acquisition of crops as legally required; control stocks, transfer, import and export; and support estimates and statistical reporting to the International Narcotics Control Board.

1.4 Health research and medicines

Law No. 6/2023 applies to human health research and identifies INS, CNBS, ANARME and the multi-institutional inspection body. Decree No. 17/2023 separately governs clinical trials. Lawful possession of a controlled plant does not authorise manufacture or human use. The programme will therefore use separate pharmaceutical, ethics and clinical-trial gates.

2. Enabling Legal Instrument

RECOMMENDED LEGAL ROUTE: A published Council of Ministers decree establishing a narrow medical/scientific pilot and a project-specific licence issued under that instrument. If Justice/PGR concludes that Law No. 3/97 does not provide sufficient delegated authority, the project must wait for a legislative amendment.

2.1 Minimum contents of the decree

- Purpose, scope, duration and non-commercial character of the pilot.
- Definitions covering plant, cannabis, resin, extract, cannabinoid, research material, investigational product, waste, national agency and licensee.
- Designation and powers of the national cannabis control agency.
- Licensing procedure, application contents, fit-and-proper requirements and fees.
- Designation of licensed research areas, plots and maximum authorised quantities.
- State crop-control, custody/acquisition, inventory and INCB reporting arrangements.
- Security, inspection, chain-of-custody, transport, loss reporting and destruction requirements.
- Separation of cultivation, pharmaceutical manufacture, clinical research and market authorisation.
- Suspension, revocation, seizure, administrative sanctions and appeal.
- Transitional and commencement provisions, including an express prohibition on planting before an effective project licence and readiness certificate.

2.2 Project-specific authorisation schedule

Authorisation field	Required project-specific entry
Licensee	Recognised Mozambican public research institution and responsible officers
Site	Cadastral coordinates, facility plan, authorised rooms/plots and excluded areas
Material	Species, accession/genetics, source, import/collection status and maximum quantities
Permitted acts	Each permitted act separately: acquire, possess, cultivate, sample, test, transport, store, extract, manufacture or destroy
People	Named or role-approved personnel, background checks, training and access level
Controls	Inventory, state crop control, reports, surveillance, independent testing, inspections and destruction
Limitations	No sale, supply, promotion, contract farming, personal use or human administration

3. Institutional and Governance Model

The safest custody model places the controlled material under a recognised Mozambican public institution. A private sponsor may fund and manage non-controlled work but should not possess controlled material unless it is separately identified and authorised.

Body	Primary mandate	Mandatory outputs
Council of Ministers	Create lawful pilot framework and policy mandate	Published instrument; designation of lead authority
National control authority / GCPCD-led coordination	Controlled-plant licensing, diversion prevention, treaty reporting	Licence, inspections, inventories, incident decisions, INCB data

Body	Primary mandate	Mandatory outputs
Health authority / ANARME	Medicines, pharmaceutical entities, trials, AIM	Classification, facility licence, trial decision, market decision
INS / CNBS	Health-research regulation and ethics	Registration, scientific/ethical approvals and monitoring
Agriculture / IIAM / plant-health authority	Research genetics, seed and phytosanitary control	Seed/collection authorisation, inspections and certificates
Interior / Police / SERNIC / Customs	Security, criminal-risk controls and border movements	Security approval, transport/import controls and incident support
Public institutional licensee	Legal custody and scientific execution	Protocols, personnel control, records, reports and compliance
Private sponsor	Finance and technical support within licence boundaries	Funding, procurement integrity, technology transfer and audit support

3.1 Independent compliance function

- A compliance officer approved by the steering committee and independent of production targets.
- Direct reporting access to the licence authority, institutional head and audit committee.
- Authority to quarantine material and stop work without commercial approval.
- Monthly reconciliation and quarterly independent compliance audits.
- Mandatory disclosure of conflicts of interest, beneficial ownership and related-party procurement.

4. Programme Scope, Work Packages and Phases

SCOPE CONTROL: The programme starts as a regulatory and scientific research programme. References in the earlier project documents to 1-10 hectares, seed multiplication, community contract growing, oil trials, hempcrete, off-takers, exports or revenue are excluded from the authorised pilot.

Phase	Purpose	Entry condition	Authorised output
0 - Regulatory mobilisation	Legal instrument, partners, site and dossiers	Government accepts pre-application	No controlled material
1 - Licensing and readiness	Obtain all authorisations and qualify facility	Enabling framework published	Readiness certificate
2 - Controlled characterisation	Minimal authorised cultivation and analytical profiling	Project licence plus all site/seed/ABS approvals	Validated research data and controlled samples
3 - Product development	Standardised investigational product	ANARME classification and facility permissions	Nonclinical/CMC dossier
4 - Clinical evaluation	Approved trial in defined indication	Ethics, INS and ANARME approvals	Clinical evidence only
5 - Close-out/policy decision	Destroy/transfer stocks and evaluate future law	Regulator-directed close-out	Final report; no automatic commercial right

4.1 Work Package A - Legal and regulatory establishment

- Consolidated Mozambican legal opinion and gazette verification.
- Draft enabling instrument, licence form, inspection checklist and reporting rules.
- Treaty-control plan, annual estimates and statistical reporting responsibilities.
- Pre-application consultations and written interpretations from each authority.

4.2 Work Package B - Site and facility qualification

- Verified DUAT or lawful institutional land-use authority.
- Exact cadastral coordinates and conservation/protection-zone screening.
- Environmental categorisation, licence and management plan.
- Secure perimeter, controlled entry, alarm, backup power, evidence-grade surveillance and secure storage.
- Validated weighing, labelling, inventory, quarantine and destruction areas.

4.3 Work Package C - Genetics, seed and benefit-sharing

- Regulator-approved source and quantity for every accession.
- Seed import permit, phytosanitary certificate, inspection and quarantine where imported.
- Prior informed consent, material transfer agreement and mutually agreed terms where landraces or traditional knowledge are accessed.
- National repository records and restrictions on onward transfer, sequence data and intellectual-property claims.

4.4 Work Package D - Controlled scientific characterisation

- Identity and accession verification; no operational cultivation recipe forms part of this submission.
- Independent cannabinoid profile and method validation.

- Relevant contaminant, microbiological, stability and research-quality testing.
- Secure sample retention, transfer and regulator-directed destruction.
- No medical claims, patient supply or product promotion.

4.5 Work Package E - Pharmaceutical development

- Written ANARME classification of the intended product and regulatory pathway.
- Licensed pharmaceutical facility and explicit controlled-substance permission for extraction/manufacture.
- Quality target product profile, specifications, validated methods, stability and batch release.
- Pharmacology, toxicology and nonclinical evidence appropriate to the proposed trial.
- Investigator's brochure and investigational medicinal product dossier.

4.6 Work Package F - Clinical research, only if separately approved

- One defined indication, dose form, route, population and scientific hypothesis.
- Technical-scientific review, CNBS/accredited ethics approval, INS registration and ANARME authorisation.
- GCP-qualified investigators and site, insurance, informed consent and participant compensation.
- Controlled pharmacy accountability, safety reporting, monitoring, audit and data integrity.
- No recruitment, advertising or administration before every approval is effective.

5. Controlled-Substance Compliance System

5.1 Chain of custody and inventory

- Unique identifier applied at the first authorised receipt or collection event.
- Perpetual electronic inventory with immutable audit log and daily transaction recording.
- Dual-person verification for receipt, transfer, sampling, stock adjustment and destruction.
- Monthly physical reconciliation and immediate escalation of any discrepancy.
- Records retained for the statutory period or, if the decree is silent, at least ten years after close-out.

5.2 Security and personnel

- Role-based access; no unescorted visitor access to controlled areas.
- Identity and background checks to the extent permitted by law.
- Documented induction, annual refresher and competency assessment.
- 24-hour alarms and surveillance with protected evidence retention.
- Incident command plan coordinated with Police/SERNIC, GCPCD and institutional security.

5.3 Transport, import and export

- No movement without an approved consignment, destination, route, vehicle, personnel and time window.
- Tamper-evident packaging, dispatch/receipt weights and signed chain-of-custody forms.
- Separate controlled-drug, customs, seed/phytosanitary and pharmaceutical import/export permissions as applicable.
- No courier, passenger luggage or informal cross-border movement.

5.4 Quarantine, waste and destruction

- All failed, excess, unauthorised or suspect material immediately quarantined.
- Destruction only by the approved method, at the approved place, with authorised witnesses.
- Pre- and post-destruction weights, certificate, photographs where lawful, and inventory adjustment.
- Environmental handling of solvents, chemicals, plant waste and contaminated materials.

6. Land, Environment, Water and Ponta D'Ouro

The earlier concept identifies Ponta D'Ouro. Because the area is environmentally sensitive and close to a protected marine landscape, site approval must be based on exact coordinates rather than the place name. The project shall not assume that an inland agricultural plot is outside a conservation, partial-protection, coastal, wetland or community-use restriction.

- Certified DUAT/title, cadastral extract, survey diagram and proof of lawful occupation.
- Written screening by the environmental authority and, where relevant, ANAC.
- Environmental categorisation and licence under the applicable EIA framework.
- Water-resource authorisation for boreholes, abstraction or regulated irrigation.
- Community consultation, grievance process, local authority notice and benefit commitments.

- Alternative institutional site assessment if Ponta D'Ouro creates avoidable legal or environmental delay.

7. Pharmaceutical and Clinical Compliance

NON-NEGOTIABLE SEPARATION: Controlled cultivation licence does not authorise pharmaceutical extraction; pharmaceutical licensing does not authorise a clinical trial; clinical-trial approval does not authorise sale; successful research does not create a commercial cultivation right.

Regulatory decision	Minimum evidence	Authority	Activity remains prohibited until
Product classification	Composition, intended use, claims, route and dosage form	ANARME	Written classification
Manufacturing permission	Licensed facility, GMP, quality system and controlled-substance scope	ANARME plus drug authority	Both permissions effective
Ethics and research registration	Protocol, consent, investigator, site and participant protection	CNBS/CIBS and INS	Approvals and registration effective
Clinical-trial authorisation	Preclinical evidence, investigator brochure, protocol and site documents	ANARME/Health	Written authorisation and site activation
AIM	Quality, safety, efficacy, labelling and pharmacovigilance dossier	ANARME	AIM and commercial legal basis

7.1 Clinical participant safeguards

- Voluntary, informed consent in Portuguese and any appropriate local language.
- Fair recruitment and additional protection for vulnerable participants.
- Insurance, medical care and compensation for research-related harm.
- Privacy, confidentiality, coded data, controlled access and documented data retention.
- Independent safety review proportionate to risk; prompt reporting of serious adverse events.
- Post-trial plan that does not promise continued access before lawful market or special-access authority exists.

8. Master Compliance and Approval Matrix

ID	Approval	Owner/authority	Required before	Status
A1	Consolidated legal opinion	Mozambican counsel; Justice/PGR confirmation	Before decree drafting is final	Pending
A2	Enabling pilot instrument	Council of Ministers / legislature if required	Before project licence	Pending
A3	National agency and INCB arrangements	Government-designated authority	Before production-related cultivation	Pending
A4	Project controlled-cannabis licence	Authority named in instrument	Before acquisition/possession	Pending
A5	Facility readiness certificate	Licence authority and security bodies	Before planting	Pending
A6	Public host institutional approval	Host governing body	Before licence application	Pending
A7	Research protocol approval	Institutional scientific committee	Before each work package	Pending
A8	DUAT/land-use authority	Land administration/local authority	Before site installation	Pending
A9	Environmental category/licence	Environmental authority	Before works/operation	Pending
A10	ANAC/conservation clearance	ANAC if coordinates trigger review	Before site approval	Pending
A11	Water authorisation	Relevant water authority	Before abstraction	Pending
A12	Seed/variety research permission	Agriculture/seed authority	Before seed acquisition	Pending
A13	Phytosanitary import/quarantine	National plant-health authority	Before import	Pending
A14	ABS/PIC/MAT/MTA	ABS authority and communities	Before landrace access	Pending
A15	Transport authorisation	Drug authority/Interior/Customs	Before each movement	Pending
A16	ANARME product classification	ANARME	Before product development route	Pending
A17	Pharmaceutical facility/activity licence	ANARME	Before extraction/manufacture	Pending
A18	Ethics approval	CNBS/accredited committee	Before human research	Pending
A19	INS registration/approval	INS	Before human research procedures	Pending
A20	Clinical-trial authorisation	ANARME/Health	Before recruitment/administration	Pending
A21	AIM	ANARME	Before commercial supply	Not in pilot
A22	Commercial cannabis legal basis	Government/legislature	Before commercial cultivation	Not in pilot

9. Risk, Incident and Stop-Work Framework

Trigger	Immediate action	Notification	Restart authority
Licence absent, expired, suspended or unclear	Stop all controlled activity; secure inventory	Licence authority, host head, GCPCD	Written regulator decision
Inventory discrepancy, loss or suspected diversion	Lockdown, preserve evidence, reconcile	Police/SERNIC, GCPCD, licence authority	Joint written release
Material outside authorised specification	Quarantine and suspend affected work	Licence authority and scientific lead	Approved disposition
Security system failure	Suspend access/movement; deploy approved contingency	Security lead and licence authority	Readiness re-certification
Environmental spill or unlawful waste event	Contain, protect people/environment, stop source	Environment, local authority, licence authority	Environmental clearance
Serious adverse event in trial	Medical care, unblind if required, suspend per protocol	ANARME, ethics, sponsor, safety board	ANARME/ethics decision
Commercial pressure or unauthorised publicity	Remove claims; suspend related engagement	Steering committee and regulators if material	Compliance clearance

10. Implementation Schedule and Conditions Precedent

The dates below are planning ranges, not promises. Government and ethics review periods cannot be guaranteed. The previously proposed July/August 2026 cultivation date must be removed unless every approval is already effective.

Planning window	Milestone	Condition to close milestone
Month 0-2	Legal opinion, institutional partner, site coordinates, pre-application package	Written partner mandate and regulator meeting record
Month 2-9+	Enabling instrument and national control arrangements	Publication/effective legal authority
After legal framework	Project application, land/environment/seed/ABS/security approvals	All A1-A15 approvals effective
2-3 months after licence	Facility qualification and readiness inspection	Readiness certificate
Approximately 12 months	Controlled characterisation programme	Approved data and reconciled inventory
Approximately 12-18 months	Pharmaceutical/nonclinical development	ANARME-acceptable dossier
Only after separate approvals	Clinical evaluation	Trial close-out and final report

10.1 Conditions precedent to first seed or plant

- Enabling legal instrument effective and verified by counsel.
- Project licence effective and covering acquisition, possession and cultivation.
- National agency, crop-control and INCB arrangements operational.
- Public institutional licensee and responsible officers formally appointed.
- DUAT/land authority, environmental licence and conservation clearance complete.
- Seed, phytosanitary and ABS permissions complete for the identified material.
- Security, inventory, transport, destruction and emergency SOPs approved.
- Facility inspection passed and readiness certificate issued.
- Insurance, funding and procurement controls effective.
- Written notice to proceed signed by the licence authority and institutional head.

11. Budget Framework, Monitoring and Public Value

No cultivation revenue is included in the pilot budget. Funding shall be ring-fenced, auditable and sufficient to complete compliant destruction and close-out even if the programme is suspended.

Budget category	Included costs	Control
Legal/regulatory	Counsel, gazette review, drafting, applications, regulator meetings	No success fees linked to approval
Public institution	Scientific leadership, facilities, governance and administration	Transparent institutional agreement
Security/compliance	Facility controls, surveillance, audit, inventory and destruction	Ring-fenced close-out reserve
Scientific/laboratory	Validated methods, testing, reference standards and quality systems	Approved laboratories and procurement
Environment/ community/ABS	Screening, licences, consultation and benefit-sharing	Documented commitments and grievance review
Pharmaceutical/clinical	GMP, nonclinical, insurance, ethics, trial and pharmacovigilance	Activated only after regulatory approval

Budget category	Included costs	Control
Contingency/close-out	Quarantine, destruction, data archiving and site remediation	Cannot be used for expansion

11.1 Key compliance indicators

Indicator	Target	Escalation threshold
Unlicensed controlled acts	Zero	Any event: immediate stop-work
Inventory reconciliation	100%	Any unexplained variance
Authorised personnel training	100% before access	Any untrained access
Regulatory reports submitted on time	100%	Any missed statutory deadline
Protocol deviations	Zero major; all documented	Major or repeated deviation
Participant serious safety reports	Within required timelines	Any late or incomplete report
Community grievances	Acknowledged and resolved under plan	Unresolved material grievance

12. Government Submission Dossier

No.	Dossier component	Required content
1	Formal covering request	Sponsor and public host; decision requested and non-commercial status
2	Consolidated legal opinion	Authority, legal form, criminal exposure and full approval map
3	Draft enabling instrument	Article-by-article decree plus explanatory memorandum
4	Draft project licence	Named activities, site, material, quantities, people and controls
5	Treaty-control memorandum	National agency functions, estimates, crop custody and INCB reporting
6	Scientific master protocol	Objectives, work packages, methods, limits and decision rules
7	Institutional agreements	Public host, sponsor, laboratories, manufacturers and accountability
8	Site dossier	DUAT, coordinates, layout, environmental/conservation screening and water
9	Genetics/seed/ABS dossier	Provenance, permits, PIC, MAT, MTA and benefit-sharing
10	Security plan	Access, surveillance, incident command, transport and evidence retention
11	Controlled-substance management plan	Inventory, state custody, sampling, reporting and destruction
12	Quality management plan	Document control, training, deviations, CAPA, audit and laboratories
13	Environmental/social plan	Waste, spill response, community engagement and grievance mechanism
14	Pharmaceutical development plan	Classification request, CMC, GMP, nonclinical and stability
15	Clinical-development plan	Only prospective; ethics, GCP, safety, insurance and consent
16	Finance and integrity dossier	Funding, beneficial ownership, procurement and close-out reserve
17	Communications plan	No promotion or medical claims before lawful approvals
18	Approval matrix and signed conditions precedent	No activity until each applicable gate is green

13. Integration of the Existing IRBI Documents

The existing IRBI materials remain useful as development and advocacy background, but they must be subordinated to this approval programme. The two Executive Summary files reviewed are duplicates.

Existing document	Permitted use	Required correction
Executive Summary IRBI	National-development rationale and stakeholder briefing	Insert legal gates; no implication that research approval legalises cannabis
Ponta D'Ouro Bioeconomy Pilot	Background only	Replace commercial/agricultural rollout with the controlled phased programme
Annex 1 compliance checklist	Source checklist	Replace speculative 'special authorisation' with enabling instrument and licence
Integrated Rural Bioeconomy Initiative	Ministerial narrative after legal review	Remove premature medical, product, investment or legal-status claims

Appendix A - Mandatory Instructions to Mozambican Legal Counsel

6. Confirm the consolidated status of Law No. 3/97, its schedules, amendments and implementing instruments.
7. Identify the authority legally competent to authorise cultivation, possession, sampling, transport, extraction, manufacture, import, export and destruction.
8. Determine whether a Council of Ministers decree is sufficient or a parliamentary amendment is required.
9. Determine whether the authorisation must be published in the Boletim da República.
10. Specify the legal status of CBD, THC, low-THC plants, extracts, reference standards and waste.
11. Define the national agency structure required by Articles 23 and 28 of the Single Convention.
12. Map criminal and administrative exposure for directors, employees, investigators, landlords, contractors and public officers.
13. Confirm the roles of GCPCD, Health, ANARME, INS, Agriculture, Interior, Customs, Environment and provincial/local authorities.
14. Confirm every seed, phytosanitary, ABS, DUAT, environmental, water and conservation requirement.
15. Confirm the lawful form of government crop custody/acquisition and onward transfer to an authorised laboratory.
16. Confirm pharmaceutical, clinical-trial, import and special-access pathways for the proposed investigational product.
17. Confirm procurement, anti-corruption, beneficial-ownership, insurance, banking, AML, tax and investor-disclosure requirements.
18. Confirm IP, traditional-knowledge, genetic-data, publication and benefit-sharing requirements.
19. Provide a signed no-go list and conditions precedent for each controlled activity.

Appendix B - Draft Structure of the Enabling Instrument

Article	Subject	Required substance
1	Object	Establish the national, non-commercial medical/scientific pilot.
2	Scope	Apply to all institutions, persons, sites and controlled material in the pilot.
3	Definitions	Define cannabis, plant, resin, extract, cannabinoid, agency, licence and product.
4	National agency	Designation, powers, records, crop control, treaty and INCB functions.
5	Steering committee	Interministerial membership, decision and reporting functions.
6	Licensed areas	Method for designating approved research areas and premises.
7	Licensing	Eligibility, application, fit-and-proper review, fees and decision.
8	Licence conditions	Material, quantity, acts, people, security, records and duration.
9	Crop control	State custody/acquisition, stocks, transfer, sampling and destruction.
10	Security and transport	Access, surveillance, approved movement and incident notification.
11	Import/export	Drug, customs, phytosanitary and pharmaceutical authorisations.
12	Research-only restriction	No sale, supply, personal use, promotion or contract growing.
13	Agriculture and ABS	Seed, plant health, landrace and benefit-sharing compliance.
14	Medicines and manufacture	ANARME classification and separate facility/activity licences.
15	Human research	Law No. 6/2023, ethics, INS and Decree No. 17/2023 controls.
16	Inspection and audit	Unannounced access, sampling, records and corrective actions.
17	Suspension/revocation	Triggers, quarantine, seizure, close-out and appeal.
18	Reporting	Periodic, incident, annual estimate and statistical reports.
19	Offences/sanctions	Applicable administrative/criminal consequences within legal competence.
20	Commencement	No controlled activity before project licence and readiness certificate.

Appendix C - Final Go/No-Go Certificate

The first controlled activity may proceed only when the institutional head and licence authority sign a certificate confirming that every applicable condition below is complete and effective.

- Enabling legal instrument effective and verified by counsel.
- Project licence effective and covering acquisition, possession and cultivation.
- National agency, crop-control and INCB arrangements operational.
- Public institutional licensee and responsible officers formally appointed.
- DUAT/land authority, environmental licence and conservation clearance complete.
- Seed, phytosanitary and ABS permissions complete for the identified material.
- Security, inventory, transport, destruction and emergency SOPs approved.
- Facility inspection passed and readiness certificate issued.
- Insurance, funding and procurement controls effective.
- Written notice to proceed signed by the licence authority and institutional head.
- No licence condition is ambiguous or dependent on a future approval.
- All personnel have signed compliance undertakings and completed training.
- Initial inventory has been opened at zero and tested under a mock reconciliation.
- Regulators have the final emergency contacts and inspection access.

Head of Public Institution	Licence Authority	Independent Compliance Officer

Legal Sources and Verification Record

The public-source legal review was current to 29 July 2026. The formal Mozambican legal opinion must verify the complete Boletim da República and any administrative instruments not publicly indexed. The links below are provided for verification and do not replace official certified copies.

1. **Law No. 3/97 of 13 March - Narcotic and Psychotropic Substances:** https://reformar.co.mz/documentos-diversos/lei-3-97-de-13-de-marco-criacao-da-lei-de-psicotropicos-e-estupefacientes.pdf
2. **Decree No. 28/2023 - Organic Statute of GCPCD:** https://iaom.gov.mz/wp-content/uploads/2023/06/BR_99_I_SERIE_2023-Define-o-preco-al-Algodao-campanha-22_23-Editado.pdf
3. **UNODC support for revision of Mozambique's drug law, December 2025:** https://mozambique.un.org/pt/308810-o-unodc-apoia-mo%C3%A7ambique-na-revis%C3%A3o-da-sua-lei-nacional-sobre-drogas-para-refor%C3%A7ar-resposta
4. **UN Treaty Collection - Single Convention on Narcotic Drugs as amended:** https://treaties.un.org/Pages/ViewDetails.aspx?chapter=6&mtdsg_no=VI-18&src=TREATY
5. **UNODC - Single Convention on Narcotic Drugs, 1961:** https://www.unodc.org/pdf/convention_1961_en.pdf
6. **Law No. 6/2023 - Human Health Research:** https://faolex.fao.org/docs/pdf/moz228470.pdf
7. **Decree No. 53/2024 - Regulation of the Human Health Research Law:** https://ins.gov.mz/wp-content/uploads/2025/05/Decreto_nr53_2024.pdf
8. **ANARME - Clinical trial requirements and Decree No. 17/2023:** https://anarme.gov.mz/ensaios-clinicos/
9. **ANARME - Market Authorisation (AIM):** https://anarme.gov.mz/autorizacao-de-entrada-no-mercado-aim/
10. **ANARME - Inspection and licensing of pharmaceutical entities:** https://anarme.gov.mz/inspeccao-e-licenciamento-de-entidades/
11. **Decree No. 12/2013 - Seed Regulation:** https://www.agricultura.gov.mz/wp-content/uploads/2017/12/Regulamento_Sementes.pdf
12. **Decree No. 5/2009 - Phytosanitary Inspection and Plant Quarantine:** https://www.agricultura.gov.mz/wp-content/uploads/2018/01/Decreto_5_2009_regulamento_fitosanitario.pdf
13. **Decree No. 19/2007 - Access and Benefit-Sharing for Genetic Resources:** https://sibmoz.gov.mz/content/uploads/2025/11/Decreto-no.-192007-Regulamento-sobre-o-Acesso-e-Partilha-de-Beneficios-dos-Recursos-Geneticos.pdf
14. **Decree No. 54/2015 - Environmental Impact Assessment:** https://faolex.fao.org/docs/pdf/moz174566.pdf
15. **ANAC - Ponta do Ouro Partial Marine Reserve:** https://www.anac.gov.mz/parques/ponta-do-ouro/

Final Approval Position

LAUNCH DECISION: Phase 0 may begin immediately as a non-controlled regulatory programme. No seed, plant, extract, reference sample or cannabinoid product may be acquired, possessed, cultivated, transported, extracted, manufactured or administered until the exact activity is covered by an effective written authorisation and every applicable condition precedent in this programme has been satisfied.

This design gives the Government a narrow, controlled and treaty-compatible route to approve research without creating an unregulated commercial cannabis market. Approval remains a sovereign government decision.