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Act

No. 6 of 2020

I assent

PROF. ARTHUR PETER MUTHARIKA
PRESIDENT
30TH APRIL, 2020

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An Act to make provision for regulation of research, cultivation, production, processing, possession, storage, exportation, importation, sale, distribution, and use of cannabis and its products for medicinal, industrial or scientific purposes under prescribed conditions and to provide for matters connected therewith and incidental thereto

ENACTED by the Parliament of Malaŵi as follows—

PART I—PRELIMINARY

1. This Act may be cited as the Cannabis Regulation Act, 2020 and shall come into operation on a date the Minister may, by notice published in the *Gazette*, appoint.

Short title
and
commence-
ment

2. In this Act, unless the context otherwise requires—

Interpretation

“Authority” means the Cannabis Regulatory Authority as established under section 3 of this Act;

“cannabis” means medicinal cannabis or industrial hemp;

“cannabis isolate” means a powder or crystal, in solid form at room temperature of twenty-two degrees Celsius or negative two degrees Celsius, that contains isolated elements of any cannabinoid compound in its natural form;

“cannabis crude oil” means a concentrated crude oil after processing of the cannabis flowers, in liquid form at room temperature of twenty-two degrees Celsius or negative two degrees Celsius, that will contain concentrated amounts of cannabinoids and terpenes in their natural form;

“caregiver” means a person who is providing care to a minor qualified patient or a critically ill qualified patient and is permitted to access medicinal cannabis on behalf of the qualified patient;

“Chairperson” means a Chairperson of the Authority appointed pursuant to section 4;

“child” has the meaning ascribed to that term under the Constitution;

“Deputy Chairperson” means the Deputy Chairperson of the Authority appointed pursuant to section 4;

“industrial hemp” means a cannabis plant, or any part thereof, with a *delta-9 tetrahydrocannabinol* (THC) concentration of no more than 1% in the plant material or such other concentration as may be prescribed by the Minister by order published in the *Gazette*, and may include—

(a) any fibre extracted from the plant for use as or in the manufacture of cordage, canvas or similar products;

(b) any seed which has been crushed, comminuted or otherwise processed in such a manner as to prevent germination;

(c) the fixed oil obtained from the seed;

(d) any flowers that has been processed into extracts or isolates for use in industrial applications;

“inspector” means a person appointed or designated as an inspector pursuant to section 45;

“licensee” means a person licensed under this Act and includes a permit holder issued under this Act;

“*marijuana (chamba)*” means all parts of the cannabis plant from which resin has not been extracted and includes any resin obtained from that plant but does not include—

(a) medicinal preparations made from that plant; or

(b) industrial hemp;

Cap. 36:01

“medical practitioner” bears the meaning of the term as ascribed under the Medical Practitioners and Dentist Registration Act;

“medicinal cannabis” refers to final medicinal products that are approved to help alleviate the suffering of patients, including the processed cannabis flowers, extracts, resin, crude oil, distillate and isolates that are utilized in an approved medical product with the relevant licensing and certification;

“qualified patient” means an individual who has a medical condition and has a medical recommendation to use medicinal cannabis and is identified and tracked through Registry Identification Cards (RIC) maintained by the Authority;

“Registrar” means the Director General of the Cannabis Regulatory Authority appointed under section 17;

“Registry Identification Card” means a registry identification card issued by the Authority;

“research and development” means research, seed selection, seed and plant propagation, breeding, processing, cultivation, harvesting, drying, extraction, packaging, labeling, storage and processing of cannabis;

“scientific use” means activities performed to acquire, develop or demonstrate knowledge or techniques, including teaching, field trials, environmental studies, and other uses of similar nature as the Minister may, by notice published in the *Gazette*, designate;

“THC” means delta-9 tetrahydrocannabinol (6aR, 10aR)-6a, 7, 8, 10a-tetrahydro-6, 6, 9-trimethyl-3-pentyl-6H-dibenzo (b,d) pyran-1-ol (THC) which is the psychoactive group of cannabinoid compounds in the cannabis plant and is what is controlled for medicinal use; and

“value addition” means the processing of the cannabis plant from raw bio-mass into a semi or fully processed material.

PART II—THE CANNABIS REGULATORY AUTHORITY

3. There is hereby established an Authority to be known as the Cannabis Regulatory Authority (hereinafter, referred to as the “Authority”) which shall be a body corporate with perpetual succession and a common seal and be capable of—

Establishment
of Cannabis
Regulatory
Authority

(a) acquiring, holding and disposing of real and personal property;

(b) suing and being sued in its own name; and

(c) doing or performing all such acts and things as bodies corporate may by law do or perform.

4.—(1) The Board of the Authority shall consist of—

Composition

(a) a Chairperson appointed by the Minister;

(b) four other members appointed by the Minister in consultation with relevant professional and other bodies; and

(c) as *ex-officio* members,—

(i) the Secretary responsible for Trade;

(ii) the Secretary responsible for Agriculture;

(iii) the Secretary responsible for Health;

(iv) the Solicitor General;

(v) the Inspector General of Police; and

(vi) the Director General of the Pharmacy and Medicines Regulatory Authority.

(2) A member of the Authority, other than the *ex-officio* member shall not, by reason only of his appointment as a member of the Authority, be deemed to be an employee in the public service.

(3) The Minister shall publish names of all members of the Authority, as first constituted, and every change in the membership, in the *Gazette*.

(4) A person, other than an *ex-officio* member shall not be qualified for appointment as a member of the Authority, if he—

(a) does not possess expertise and experience in a field relevant to the functions and responsibilities of the Authority;

(b) is a public officer or a member or employee in a public institution;

(c) is adjudged or declared bankrupt; and

(e) would for any other reason be disqualified by law from serving as a director of a company or as trustee.

(5) The Secretary responsible for Trade shall be the Deputy Chairperson of the Authority.

(6) At least three members of the Authority appointed under subsection (1) shall be women.

Tenure and
vacancies

5.—(1) A member of the Authority, other than an *ex-officio* member, shall hold office for a period of two years and is eligible for re-appointment for a further term or terms of two years.

(2) When making an appointment after the expiry of two years, the Minister shall have regard to the need for continuity in the membership of the Authority so that at least half of the appointed members shall be re-appointed for the next term of office.

(3) A vacancy in the office of a member of the Authority shall occur, if the member—

(a) dies;

(b) is adjudged or declared bankrupt;

(c) is convicted and sentenced for an offence against any written law to a term of imprisonment without an option of a fine;

(d) fails, without good and justifiable reasons, to attend three consecutive meetings of the Authority of which he had notice;

(e) is certified by a medical practitioner to be incapacitated by reason of physical or mental illness;

(f) resigns in accordance with subsection (4);

(g) is removed by the Minister in accordance with subsection (5); or

(h) if a situation arises that if the person was not appointed, would have disqualified him from being appointed as a member of the Authority.

(4) A member of the Authority, other than an *ex-officio* member, may at any time resign his office by giving one month written notice to the Chairperson, who shall forward the resignation to the Minister.

(5) The Minister may remove any member of the Authority, except an *ex-officio* member, of the Authority on any of the following grounds—

(a) misconduct that brings the office of the member or the Authority into disrepute;

(b) incompetence in the execution of the functions of his office as a member of the Authority;

(c) in circumstances where the member is compromised to the extent that his ability to impartially and effectively exercise the duties of his office is seriously in question.

(6) A vacancy in the membership on the Authority shall be filled by the appointment of a new member by the Minister in accordance with section 4 (1).

(7) A person appointed to fill a vacancy shall serve for the remainder of the term of office but no person may be appointed to fill a vacancy of the remainder of a term of office where the remainder of the term is less than six months.

(8) The period served by a person appointed under subsection (6) shall not be regarded as a term for the purposes of subsection (1).

(9) Subject to section 11 (4), a vacancy in the membership of the Authority shall not affect its decisions, the performance of its functions or the exercise of its powers under this Act or any other written law.

6.—(1) The Authority may, for the better carrying into effect of its functions, establish such number of committees as may be considered necessary to perform such functions and responsibilities as may be determined by the Authority.

Committees
of the Board

(2) A committee may consist of either members of the Authority only or members of the Authority and such other suitably qualified persons other than members of staff of the Authority as the Authority may deem fit.

(3) The Authority shall appoint the chairperson and deputy chairperson of each committee from only amongst the members of the Authority.

(4) The provisions of this Act relating to the meetings of members of the Authority shall apply *mutatis mutandis* to the meetings of its committees.

(5) Every committee shall act in accordance with any directions given to it in writing by the Authority.

Allowances
and expenses

7.—(1) Members of the Authority and of any of its committees shall be paid allowances as the Minister may determine.

(2) The Authority shall provide for the reimbursement of any reasonable expenses incurred by a member of the Authority or a member of a committee or a person invited under section 11 (7) in connection with the business of the Authority or a committee.

Functional
independence
of the
Authority

8.—(1) Every member, member of a committee or member of staff of the Authority shall perform the functions and exercise the powers provided for in this Act under the general direction of the Minister but shall be independent of the undue influence or interference of—

(a) any political party; or

(b) any person whatsoever or organization whatsoever.

(2) For purposes of accountability, the Authority shall be answerable, and report bi-annually and directly to the Minister on the overall activities of the Authority.

Functions of
the Authority

9. The functions of the Authority shall be to—

(a) regulate the cultivation, propagation, production, processing, storage, exportation, importation, distribution and use of cannabis;

(b) advise the Minister on all technical matters regarding cannabis;

(c) issue general and specific guidelines and directives to the secretariat of the Authority in relation to this Act;

(d) establish rules of procedures for the Authority;

(e) review and approve test guidelines pursuant to this Act;

(f) review and recommend budgetary proposals for the Authority;

(g) promote the participation of indigenous Malawians in the cultivation, propagation, production, processing, storage, exportation, importation, distribution and use of cannabis, directly or through partnerships, co-operatives or other modes of participation;

(h) perform any other functions in relation to the regulation of cannabis as it may deem appropriate for achieving the purposes of this Act.

10. The Authority shall, in the discharge of its functions, have power to— Powers of the Authority

(a) issue, review, approve or revoke a licence or permit pursuant to this Act;

(b) prescribe the numbers of licences or permits to be issued under this Act;

(c) impose penalties to any person pursuant to this Act;

(d) inspect any site or premises in connection with the implementation of this Act or any written law;

(e) ensure that the cultivation, propagation, production, processing, storage, exportation, importation, distribution and use of cannabis does not involve children;

(f) appoint or designate analysts to perform prescribed functions under this Act;

(g) engage persons of suitable qualifications and experience as consultants to the Authority;

(h) request any person to produce any document or information which, in the opinion of the Authority, is necessary for the execution of its functions under this Act;

(i) promote its functions and objectives, or any matter under its consideration, through sponsorship, support or organization of conferences, workshops or meetings;

(j) receive donations of funds, materials and technical assistance for the furtherance of its work;

(k) carry out consultations regarding any matter under its consideration and for the general conduct of its work and determine the procedure for carrying out such consultations; and

(l) do and perform all such things or acts as are necessary or expedient for the execution of its functions, duties and powers under this Act.

11.—(1) The Authority shall meet at least once every three months at a place and at a time as the Chairperson may determine. Meetings

(2) The Chairperson shall convene ordinary meetings of the Authority by giving the members of the Authority a written notice of not less than fourteen days.

(3) The Chairperson may, on his own motion and a written notice of less than fourteen days, convene an extraordinary meeting of the Authority at a place and time as he may determine in consultation with the Director General.

(4) The Chairperson shall at the written request of more than three members of the Authority and within seven days of a request, call for an extraordinary meeting of the Authority, at a place and time as the Chairperson may determine, in consultation with the Director General.

(5) The quorum at every meeting of the Authority or a committee shall be constituted by a simple majority of the total membership of the Authority.

(6) The Chairperson or, in his absence, the Deputy Chairperson, shall preside at all meetings of the Authority:

Provided that in the absence of both the Chairperson and Deputy Chairperson at a particular meeting of the Authority, the members of the Authority present and forming a quorum shall elect one of their number to preside over the meeting of the Authority.

(7) At any meeting of the Authority, the decision of the Authority on any matter shall be that of the majority of the members of the Authority present and voting, and at all the meetings, the person presiding shall have, in the event of an equality of votes, a casting vote in addition to a deliberative vote.

(8) The Authority may, where necessary taking into account the nature of the matter to be deliberated, invite any person to attend a meeting of the Authority or any of its committees and participate in the deliberations or to make a presentation or to be asked questions, on any matter, but the person so invited shall not be entitled to vote.

(9) Minutes of each meeting of the Authority or a committee shall be kept by the Registrar and shall be confirmed at the subsequent meeting of the Authority or committee, as the case may be.

(10) Subject to the provisions of this Act, the Authority may make rules to regulate its proceedings and business or the proceedings and business of any of its committees.

12. A member of the Authority or committee, other than an *ex-officio* member, shall attend a meeting of the Authority or committee in person and where such member of the Authority is unable to attend any meeting of the Authority or committee, he shall send his apologies to attend the meeting to be recorded.

Personal
attendance of
meetings

13.—(1) If a member, member of a committee or staff of the Authority, is present at a meeting of the Authority or at a meeting of a committee at which any matter which is the subject of consideration is a matter in which that person or his immediate family member or his professional or business partner is directly or indirectly interested, he shall, as soon as practicable, after the commencement of the meeting, disclose his interest and that member shall not take part in any consideration or discussion of, or vote on, any question relating to the matter.

Disclosure of interest

(2) A disclosure of interest by a member of the Authority or a committee shall be recorded in the minutes of the meeting at which it is made.

14. Every member, member of a committee, member of staff, service provider of the Authority or person invited under section 11 (7), shall, upon assumption of his office, or before attending a meeting, take an oath of confidentiality in the form set out in the Schedule to this Act and the oath shall be administered by a Commissioner of oaths.

Oath of confidentiality

15.—(1) A person shall not bring a court action or other proceedings personally against any member, a member of a committee or member of staff of the Authority in respect of any act or omission done in good faith in the course of carrying out the provisions of this Act.

Protection from liability

(2) Where, in any proceedings, a question arises on whether or not an act or an omission was done in good faith in the course of carrying out the provisions of this Act, the burden of proving that the act or the omission was not done in good faith in the course of carrying out the provision of this Act shall be on the person alleging that it was not so done.

PART III—ADMINISTRATION

16. The secretariat of the Authority shall consist of the Director General and other members of staff of the Authority appointed under this Act.

Secretariat

17.—(1) The Director General shall be appointed by the Authority through an open and competitive process on terms and conditions as the Authority may, in consultation with the Minister, determine.

Director General

(2) The office of the Director General shall be a public office.

(3) A person shall not be appointed as Director General, unless he—

(a) possesses a minimum qualification of a master's degree or its equivalent obtained subsequent to a bachelor's degree from an accredited or recognized educational institution;

(b) has expertise and experience for a period of not less than ten years at a senior position in a field relevant to the functions and responsibilities of the Authority; and

(c) does not hold a position of a political nature.

(4) The Director General shall hold office for a term of five years and is eligible for re-appointment for another term or terms of five years.

Duties and
responsibilities
of Director
General

18.—(1) Subject to the general and special directions of the Authority, the Director General shall be responsible for—

(a) day-to-day administration and management of the affairs of the Authority and in all matters shall, at all times, be subject to the directions of the Authority;

(b) regulating all matters relating to the research, cultivation, possession, production, processing, storage, exportation, importation, supply, distribution and use of cannabis;

(c) receiving applications and issuing licenses on behalf of the Authority and other authorizations in relation to research, cultivation, seed and plant propagation, supply, possession, production, storage, exportation, importation and use of cannabis for medicinal, industrial and scientific purposes in accordance with the Act;

(d) developing enforcement procedures in relation to the inspection of premises that are operated by licensees in order to ensure compliance with the provisions of this Act;

(e) establishing and maintaining an electronic database relating to licensees and provide for electronic tracking of research, cultivation, seed and plant propagation, supply, possession, production, storage, exportation, importation and use of cannabis in accordance with this Act;

(f) publishing all matters relating to the application and granting of licences for cannabis;

(g) providing the distribution of educational and public awareness materials and conduct training programmes in relation to the development of cannabis;

(h) making guidelines on the sound management and effective control of all cannabis production and products;

(i) conducting efficient inspections for security and quality assurance;

(j) providing technical advice to the Authority and other institutions or organizations on all matters relating to the management and control of the cannabis industries;

(k) the effective management of the funds, property and business of the Authority;

(l) the administration, organization and control of the other officers and staff of the Authority; and

(m) the effective administration and implementation of the provisions of this Act.

(2) The Director General shall devote his full time to the duties of his office and shall ensure that the Authority is provided with all the information, data, statistics, documents and other materials pertinent to the efficient performance by the Authority of its functions and responsibilities under this Act or any other written law.

19.—(1) The Authority may remove the Director General from office on the following grounds—

Removal of
Director
General

(a) misconduct that brings the office of the Director General or the Authority into disrepute;

(b) incompetence in the execution of his functions as Director General;

(c) incapacity by reason of physical or mental illness as certified by a medical practitioner or medical board;

(d) if he is declared or adjudged bankrupt by a competent court; or

(e) if he is sentenced for an offence against any written law to any term of imprisonment without an option of a fine.

(2) The Authority shall notify the Minister in writing of its decision to remove the Director General from office under subsection (1) and the reason or reasons therefor:

Provided that before the Director General is removed from office, the Authority shall give him an opportunity to be heard.

20.—(1) The Director General shall be—

(a) the secretary to the Board of the Authority; and

(b) the Registrar of the Authority.

Secretary and
Registrar of
the Authority

(2) The Director General shall have custody of the common seal of the Authority.

(3) The Director General may, with the approval of the Authority, delegate senior members of staff of the Authority to act as secretaries to the committees of the Authority.

Staff of the
Authority

21.—(1) There shall be employed in the service of the Authority, subordinate to the Director General, other management, professional, research, technical, administrative and other support staff as the Authority shall consider necessary for the exercise of its powers and performance of its duties and functions.

(2) The staff of the Authority referred to in subsection (1) shall be appointed by the Authority on terms and conditions as the Authority shall determine in consultation with the Office of President and Cabinet:

Provided that the Authority may, by directions in writing, delegate to the Director General, the appointment of its staff in specified junior ranks and the Director General, shall report to the Authority every appointment made pursuant to this subsection.

(3) Every member of staff of the Authority shall, on first appointment, take an oath of secrecy in the form set out in the Schedule to this Act and a Commissioner of oaths shall administer the oath.

(4) The Director General or other officer of the Authority as the Authority or the Director General may designate, may attend meetings of the Authority and of any of its committees and may address the meetings, but shall not vote on any matter.

(5) Where, in any meeting, the deliberations of the Authority or any of its committee concerns the Director General or any officer of the Authority designated to attend the meeting, the Authority or the committee, as the case may be, may exclude the Director General or the officer from the meeting.

PART IV—FINANCIAL PROVISIONS

Funds of the
Authority

22.—(1) The funds of the Authority shall consist of—

(a) sums appropriated by Parliament for purposes of the Authority;

(b) sums or assets that may accrue to or vest in the Authority, as fees or charges, derived from issuance of licences or otherwise, or whether in the course of the performance by the Authority of its functions or the exercise of its powers or otherwise;

(c) sums or assets that may accrue to or vested in the Authority by way of grants, subsidies, bequests, donations, gifts and subscriptions, from the Government or any other person;

(d) sums that are received by the Authority by way of voluntary contributions;

(e) a levy imposed by the Minister responsible for Finance, by order published in the *Gazette*; and

(f) sums or assets as may be donated to the Authority by any foreign government, international agency or other external body of persons.

(2) The Authority may receive the sums or assets referred to in subsection (1) from a source other than the Government provided that no sums or assets so received shall jeopardise or compromise the independence of the Authority.

(3) The Authority shall, within a period not exceeding three months from the end of the financial year, provide the Minister responsible for finance in writing details of the sums or assets received by the Authority under subsection (1) from a source other than the Government.

(4) The Government shall adequately fund the Authority to enable it perform its functions and exercise its powers so as to ensure its independence.

(5) Subject to the Public Finance Management Act, the funds and assets of the Authority shall exclusively be under the control of the Authority and shall be utilized solely for the purposes of this Act in accordance with the written directions of the Authority and for no other purpose. Cap. 37:02

(6) The Authority shall at all times comply with the provisions of the Public Audit Act, the Public Finance Management Act and the Public Procurement and Disposal of Assets Act. Cap. 37:01
Cap. 37:02
Cap. 37:03

(7) For the purposes of this section, "an external body of persons", means any body of persons, incorporated or unincorporated, formed under or by virtue of the laws of any other country.

23.—(1) The Authority shall be liable to account to the National Assembly in the manner applicable to Government departments. Accounting
and audit

(2) The accounts of the Authority shall be liable to audit annually by the Auditor General or by independent professional auditors appointed by the Authority in consultation with the Auditor General, and the expenses of the audit shall be paid out of the funds of the Authority.

PART V—LICENCES AND PERMITS

24.—(1) A person who is not licensed or permitted under this Act or any other written law, shall not research on, cultivate, propagate, supply, possess, produce, process, store, export, import, use or distribute cannabis and its products. Requirement
for a licence

(2) A person who engages in any act in contravention of subsection (1) commits an offence.

Application for
a licence

25.—(1) The Authority may grant any of the following licences—

- (a) licence to cultivate and sell;
- (b) licence to process;
- (c) licence to store;
- (d) licence to export;
- (e) licence to distribute;

(2) A person shall not export or import cannabis unless he acquires a permit issued by the Minister.

(3) A person who intends to research on, cultivate, propagate, supply, possess, produce, store, export, import, sell or distribute cannabis may, on payment of a prescribed fee, apply to the Registrar for a licence or permit in a manner prescribed under this Act.

(4) An application for the issue of a licence or permit under subsection (3) shall be accompanied by—

(a) a business plan with the full details of activities for which the licence or authorization is being sought and specify the type of cannabis he seeks to cultivate;

(b) the associated fees for the business plan;

(c) a list of the approved plant varieties to be used for cannabis, including certified seed to be used, and any accompanying Certificate of Analyses;

(d) three copies of a plan of the site proposed to be used by a licensee or licensed producer, which shall comply with the requirements under this Act;

(e) proof of incorporation or registration under a written law in Malaŵi;

(f) the applicant's name, mailing address and contact details in Malaŵi and, if applicable, his telephone or fax numbers and electronic mailing address;

(g) details of the form in which the cannabis shall be imported, exported, produced, propagated, sold, provided, possessed, stored, transported, sent or delivered, as the case may be;

(h) an undertaking not to contravene section 127A of the Taxation Act with respect to transfer pricing;

(i) the address of each place or for any subsidiary companies under such a holding company where the cannabis is to be stored, sold or provided, indicating for each place the form or quantity of material;

(j) in the case of the cultivation of cannabis, details of—

(i) the approved cannabis variety or cultivar that will be sown or propagated, or the variety, if the applicant is the plant breeder, that is intended to be cultivated upon receipt of a licence;

(ii) a sample of an approved variety in Malaŵi, otherwise approval shall be granted only for small quantities of seed for evaluation by a recognized Malaŵian research institution;

(iii) the number of hectares of cannabis to be cultivated for seed or viable grain, fibre or flowers;

(iv) the number of hectares of cannabis to be cultivated for the production of medicinal products;

(v) whether the applicant intends to partner or sub-contract activities to local farmers and producers, and therefore requires the right to delegate or sub-license other entities:

Provided that the applicant shall, at all times, remain responsible for ensuring that person acting under delegated authority or a sub-licence under this Act comply with the requirements of the licence of the applicant;

(vi) the number of additional farmers or hectares to be included as additional sites under one licence;

(vii) the global positioning system coordinates of the fields where the cannabis shall be cultivated;

(viii) the address of each property, location, or premise used or proposed for use by the cannabis cultivator or producer;

(ix) in the case of the processing activities, the address of each place at which the processing will take place;

(x) a declaration, signed and dated by the applicant that it is conversant with the provisions of this Act; and

(xi) any other details as the Authority may, by notice published in the *Gazette*, prescribe.

(5) The application shall further contain a detailed description of the method that the applicant proposes to use for keeping records, which shall—

(a) ensure compliance with the record keeping requirements under this Act;

(b) permit the Registrar to audit the activities of the applicant once licensed in terms of this Act; and

(c) where applicable, contain further details of—

(i) the maximum estimated quantity expressed as the net weight (grammes, kilogrammes or tonnes) of the cannabis product to be produced, stored, possessed, sold or distributed by the applicant under the licence; and

(ii) the maximum period for which the applicant wishes to conduct its licensed activities.

(6) The application made under this section shall be accompanied by a security clearance certificate from the Malaŵi Police Service of—

(a) the applicant; and

(b) each senior officer and director of the applicant.

(7) An application under this section shall be signed by the applicant or, in the case of a body corporate, one of its officers, directors or partners, as the case may be, and indicate that all information and documents submitted in support of the application are correct and complete to the best of their knowledge.

Grant or refusal of application 26.—(1) Where the Registrar examines the application under section 25 and is—

(a) satisfied that the applicant meets the requirements of this Act, he shall submit the application to the Authority with a recommendation to grant the licence to the applicant; and

(b) not satisfied that the application has met the requirements under section 25, he shall give a written justification to the applicant why the application was not forwarded to the Authority within ninety days.

(2) Where the Registrar refuses to submit the application to the Authority, the applicant may re-submit the application to the Registrar after rectifying the shortfalls or mischief in the application cited by the Registrar in his written justification.

(3) Where the grounds for refusal to grant a licence are not in line with the principles of fairness and or natural justice, the applicant shall be entitled to a review of the decision by a competent court of law.

27.—(1) The licence or permit issued under this Act shall—

Particulars of
licence or
permit

- (a) be in the prescribed form;
- (b) be valid of a specified period;
- (c) be issued subject to payment of a prescribed fee and any other terms and conditions as the Authority to prescribe;
- (d) be published in the *Gazette*;
- (e) bear a licence or permit number;
- (f) bear the name and address of the licensee;
- (g) list the authorized activities;
- (h) bear the physical address of the site or sites and, if possible, of each building location if located in different locations but under the same licence where authorized activities may be conducted;
- (i) indicate the effective and expiry dates of the licence; and
- (j) bear any conditions which the licensee is required to meet in order to—
 - (i) provide the appropriate security level as per regulations of each industry;
 - (ii) put in place the security measures prescribed under the licence or permit according to the regulations for each industry; and
 - (iii) reduce any potential public health, safety or security risk, including the risk of products being diverted to any illicit market or use.

(2) Upon being granted the licence or permit, the licensee shall—

- (a) be entitled to engage in the activities for which the licence has been obtained;
- (b) cause a licence to be displayed, at all times, on the site to which the licence relates; and
- (c) comply with all the conditions that the licence has stipulated.

(3) A licence issued under this Act shall be valid for a period of twelve months after which it may be renewed for further period of twelve months or such period as may be prescribed by the Registrar, upon the payment of a prescribed fee.

(4) In the case of an import, export or transit permit, the validity of such licence shall not exceed four months.

(5) A person intending to renew a licence under subsection (1) shall apply to the Registrar for the renewal of the licence, at least three months prior to the expiry of the licence.

(6) A person holding a valid licence under this Act may only transfer the licence to another person with the approval, in writing, of the Authority.

(7) The Authority shall, by rules, prescribe the conditions under which a licence or permit issued under this Act may be transferred to another person.

(8) Where a licensee intends to produce, propagate process, sell, or distribute the cannabis at sites or through subsidiary entities or sub-contracted to farmers that were not included or detailed in the original licence application, he shall apply to the Registrar for an additional licence providing the detail pertaining to the site and production activities, as is required of an original licence application, with the notice reflecting the original licence number granted to the licensee.

Licensing of
legal persons

28. Subject to the powers conferred upon the Authority under section 10 (b),—

(a) the Authority shall issue a licence only to a qualifying legal person in respect of the activity for which he is licensed to do under this Act; and

(b) the Minister shall issue a permit only to a qualifying legal person in respect of the activity for which he is permitted to do under this Act.

Annual returns
to be
submitted

29.—(1) A licensee shall submit to the Registrar, on 30th June every year, records of all transactions which are required to be kept in terms of this Act.

(2) The Registrar shall prescribe the manner in which records may be submitted to him under this Act.

(3) A licensee who fails to submit to the Registrar the records, without a reasonable justification for the default, by the period specified under this section commits an offence and shall be liable to a prescribed daily penalty.

(4) The Registrar may suspend a licence where the licensee fails to submit the records within the thirty days referred to in subsection (3), on such conditions as the Authority deems fit.

(5) The Registrar may reinstate the licence suspended under subsection (4) on such conditions as he deems fit upon being satisfied that the licensee has complied with the requirement.

(6) Where the licensee fails to rectify the reasons for suspension or fails to comply with the conditions of reinstatement referred to under this section within sixty days of the date of notification, the Registrar shall cancel the licence.

30.—(1) The Registrar shall cancel a licence issued under this Act, where—

Cancellation
on other
grounds

(a) the Registrar has reasonable grounds to believe that the licence was issued on the basis of false or misleading information or false or falsified documents submitted with the application;

(b) the licensee has, since the issuance of the licence, contravened this Act or its regulations or a condition of his licence or permit issued under this Act, and has failed to remedy the contravention within a specified period;

(c) the licensee is no longer eligible as required under section 25;

(d) the information received from any competent national or international agency or under the mutual assistance corporation agreements with other national or international law enforcement partners raises reasonable grounds to believe that the licensee has been involved in the diversion of a controlled substance or precursor to an illicit market or use; or

(e) any of the persons required to have Malaŵi Police Service clearance under this Act have violated the clearance.

31.—(1) A licensee who intends to cease conducting activities at a licensed site, whether before or on the expiry of their licence, shall submit to the Registrar a written notice to that effect, at least thirty days before ceasing those activities.

Cessation of
activities

(2) The Registrar shall prescribe the manner and nature of information which a license holder shall submit to him on cessation of activities.

32.—(1) The Authority may, on written application, grant a permit to conduct a programme for a prescribed purposes that requires the import, possession or use of—

Permits for
scientific
research
purposes

(a) seed or genetic material of a specific cannabis variety to be introduced in the country for the first time; or

(b) cannabis drug or medicine.

(2) The applicant shall, in his application to conduct a programme specified under subsection (1), specify—

(a) his full name, address, academic, professional or other relevant qualifications of the applicant;

(b) in case of research purposes—

(i) the varieties of cannabis in relation to which the permit is sought;

(ii) the maximum quantity of cannabis seed per trial season;

(c) in case of medicinal purposes—

(i) the cannabis drug in relation to which the permit is sought;

(ii) the strength and form in which the cannabis drug is to be used;

(iii) the maximum quantity of the cannabis drug to be possessed at any one time, and the total quantity to be possessed during the period of the programme;

(iv) details of the manner in which the cannabis drug would be used;

(d) the name and address of the place where the programme is to be conducted;

(e) the name and academic, professional or other relevant qualifications of any person other than himself, under whose supervision the programme would be conducted; and

(f) the security arrangements that would be undertaken during the research period.

(3) An application by the applicant to conduct the programme specified under subsection (1), shall be accompanied by—

(a) a written description of the programme, including its duration;

(b) a research protocol, in the case of research;

(c) a clinical trial protocol, in the case of a clinical trial; and

(d) a written statement approving the programme, signed by the head of the institution.

(4) The Registrar may authorize the programme, if he is satisfied that—

(a) the programme is scientifically viable having regard to any relevant protocol;

(b) the applicant has a prerequisite qualification to conduct the programme;

(c) the programme will be adequately supervised by qualified personnel; and

(d) the programme is to be conducted at, or under the auspices of, a recognized institution.

(5) A permit, issued by the Registrar, shall specify—

(a) the full name and address of the authorized person;

(b) the cannabis varieties for the purpose of agricultural research or cannabis drug for medicinal purpose to which the permit relates;

(c) the strength and form in which the drug may be used;

(d) the maximum quantity of cannabis seed, or the cannabis drug that may be possessed at any time, and the total quantity that may be possessed during the period of the programme;

(e) the purpose for which the permit is granted;

(f) the institution, in relation to which the permit is granted;

(g) the conditions as are necessary and reasonable for ensuring that—

(i) the proper use and safe-keeping of the cannabis drug, cannabis seed, cannabis products; and

(ii) that proper records are kept concerning its receipt, use and disposal;

(h) the condition that such reports as the Registrar may specify are submitted to the Registrar, on the use of the cannabis drug in the programme, including particulars of the quantities acquired, used, disposed of and still held; and

(i) such other particulars as the Registrar may prescribe.

PART VI—OBLIGATIONS OF LICENSEE

Compliance
with security
measures

33.—(1) A licensee under this Act shall comply, and cause to be complied with, all the security measures prescribed under this Act.

(2) Without prejudice to the generality of subsection (1), the security measures shall aim at achieving the following—

(i) ensuring the visual security monitoring of the site at all time, either in person or electronically;

(ii) restricting persons whose presence on the site is required and implementing appropriate access control measures;

(iii) the imposition of physical barriers to prevent unauthorized access to the site through fencing or armed security guards;

(iv) detection of intrusion on the site through alarm systems or security guard patrols;

(v) monthly inspections of intrusion detection systems;

(vi) establishing and maintaining a bar coding or tagging system on every final product for the benefit of the end user;

(vii) maintaining a specified distance from a school or market as may be prescribed by the Authority; and

(viii) in the case of open field industrial hemp cultivation, the monitoring of any unauthorized access to the site and the establishment of live biological barriers, if required.

(3) The Director General shall, by notice published in the *Gazette*, prescribe the manner in which the measures stipulated in this section shall be implemented.

Production
practices

34.—(1) A licensee who produces any form of cannabis shall ensure that the production is being done in accordance with prescribed production practices, as determined by the Director General, from time to time, taking into account the on-going research results and international standards for cannabis products.

(2) Without prejudice to the generality of the subsection (1), good production practices shall include—

(a) non-involvement of children in the production, handling and processing of cannabis;

(b) good cultivation practices;

(c) nature and quality of soil or substrate;

- (d) the nature and quality of chemicals and fertilizer applied in cultivation;
- (e) the nature and quality of any extraction media;
- (f) quantity and quality of irrigation water to be used in cultivation;
- (g) nature of pesticides to be applied in cultivation;
- (h) adherence to good harvesting practices;
- (i) adherence to good post harvesting handling practices;
- (j) the permissible levels of microbial and chemicals contaminants, in line with international standards;
- (k) minimum allowable sanitation and quality assurance management systems;
- (l) testing, premises, and equipment used in respect of products;
- (m) recall, reporting and standard operating procedures; and
- (n) any other practices which the Registrar may, from time to time, prescribe as a good production practice.

35.—(1) A person shall not process cannabis unless he is registered and licensed with the Authority.

Processing of
cannabis

- (2) An application for registration shall contain the following—
- (a) a certificate of incorporation of the processor under a written law;
 - (b) the name and address of each director and shareholder of the applicant;
 - (c) the details of the shareholding of each shareholder of the processor;
 - (d) the processing capacity of the processor;
 - (e) the capacity, number and area of the warehouses of the processor;
 - (f) existing transport facilities;
 - (g) number and quality of skilled, semi-skilled and non-skilled personnel employer or to be employed by the processor;
 - (h) the precautions taken in order to preserve the environment and mitigate the impact of climate change;
 - (i) the precautions taken to prevent the involvement of children.

(3) When the particulars referred to under subsection (2) have been approved by the Authority, the Authority shall issue a licence authorizing the processing of cannabis by the processor.

(4) The processor shall, within twelve months of receiving a licence under subsection (3), start the operation of the processing factory.

Packaging

36. A licensee who produces or distributes any cannabis product shall ensure that the product is packaged in an appropriate container, in accordance with good practice, that—

(a) prevents any form of contamination;

(b) in the case of medicinal cannabis,—

(i) has a security feature that provides reasonable assurance to consumers that the container has not been opened prior to receipt; and

(ii) is child resistant.

Accuracy in
product
description

37. A licensee who produces or distributes cannabis products shall ensure that the product matches the description on the bar code and any description of the package referred to.

Product
labelling

38.—(1) A licensee shall ensure that the containers in which cannabis products are packaged, are labeled with sufficient details to trace the name and physical address of the licensee.

(2) The details shall include the brand name, batch number, recommended storage conditions, packaging date, period of usage and such other details as the Authority may prescribe.

Net weight for
containers

39. A licensee who produces cannabis for medicinal, industrial and scientific research use of the products thereof shall ensure that the net weight of the substance in the immediate container is not less nor more than what is indicated on the bar code or product container.

Shipping,
import and
export

40.—(1) A person shall not ship, export or import cannabis or cannabis products without a permit issued under this Act.

(2) A licensee who ships any cannabis product shall—

(a) only be allowed to ship value added cannabis in a semi or fully processed state not raw bio-mass;

(b) prepare the package in a manner that ensures the security of its contents;

(c) use a transport method that ensures the tracking and safe keeping of the package during transportation;

- (d) obtain the relevant export permit from the Authority;
- (e) ship the cannabis products to the shipping address that is specified; and
- (f) comply with any other shipping requirements which the Authority may prescribe.

(3) Subject to subsection (5), a licensee shall be permitted to export or import cannabis products in accordance with the listed activities and according to the requirements of the permit granted to him.

(4) The licensee shall be required to provide the following information—

- (a) for purposes of export—
 - (i) name and address of importer in the country of final destination; and
 - (ii) name of port of exit; and
- (b) for purposes of import—
 - (i) name and address of exporter in the country of origin;
 - (ii) name of port of entry; and
 - (iii) name and physical address of a site of final destination.

PART VII

LABORATORY, POSSESSION AND USAGE OF CANNABIS

41.—(1) For purposes of this Act, only the following persons are authorized to handle medicinal cannabis—

Persons
authorized to
handle
medicinal
cannabis

- (a) a licensee;
- (b) a person licensed to stock, distribute or dispense controlled medicines under the Pharmacy and Medicines Regulatory Authority Act;
- (c) any person licensed to prescribe any medicinal cannabis for medicinal purposes under the Medical Practitioners and Dentists Act;
- (d) any person working in a laboratory used for the purposes of research or instruction and attached to—

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(i) a research institution or institutions of higher education accredited or recognized under the National Council for Higher Education Act; or

(ii) a prescribed hospital;

(e) an analyst appointed under this Act, at any given time and circumstance to verify factual information in the employment by the Government;

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(f) an inspector mandated to do so pursuant to this Act and the Pharmacy and Medicines Regulatory Authority Act; or

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(g) any person authorized under the Dangerous Drugs Act.

(2) The Authority shall licence registered clinics and hospitals to issue to qualified patients and designated care givers, a Registry Identification Card, where the registered clinic or hospital is of the opinion that the qualified patient or designated care giver meets the requirements of this section.

(3) The clinics or hospitals licensed under this section shall not issue or renew a Registry Identification Card to a qualified patient under the age of eighteen years unless the qualified patient—

(a) receives an explanation from his physician regarding the potential risks and benefits of the medicinal use of cannabis and the explanation is extended to his parent, guardian or person having legal custody of the qualified patient;

(b) receives written consent from a parent, guardian or person having legal custody of the qualified patient allowing the qualified patient to use cannabis for medicinal purposes which parent, guardian or person having legal custody of the qualified patient shall also serve as one of the qualified patient's designated caregivers and controls the acquisition and taking of medicinal cannabis, the dosage and the frequency of medicinal cannabis by the qualified patient.

(4) Each Registry Identification Card, issued by the Authority, shall contain the following information—

(a) user identification number;

(b) date of issuance;

(c) date of expiration; and

(d) photo of card holder.

(5) Only a person holding a valid Registry Identification Card is authorized under this Act to use medicinal cannabis.

42.—(1) A licensee who produces, receives for research purposes, stores, distributes, imports, exports, or otherwise disposes of any form of cannabis shall keep records as prescribed by the Authority, from time to time.

Recording
keeping

(2) A licensee who conducts research on cannabis shall keep records concerning the details of the cannabis used in respect of the research and development.

(3) The Registrar shall prescribe the minimum requirements of the details to be recorded and the manner of its recording in respect of the cannabis referred to under subsections (1) and (2).

43. A licensee shall destroy or dispose of any form of cannabis or cannabis product in the presence of an inspector and an authorized officer of the MalaWi Police Service.

Destruction
or disposal

(2) A person who destroys or disposes of cannabis or a cannabis product under subsection (1) shall keep records of each instance of destruction or disposal in a manner that the Authority shall prescribe.

44. A person shall not—

(a) publish or cause to be published or brought to the notice of the public a misleading advert or conduct a pharmacy practice or conduct trade or business involving the preparation, mixing, compounding or dispensing of any cannabis product, except under the supervision of a registered pharmacist; or

(b) assume, take, exhibit or, in any way make use of, any title, emblem, description or addition reasonably calculated to suggest that he is registered under this Act, if they are not so registered.

Prohibition of
misleading
advertisement
or conducting
a pharmacy

PART VIII INSPECTION

45.—(1) The Authority shall appoint inspectors on terms and conditions determined by the Authority, with the function of checking compliance with the provisions of this Act:

Inspectors

Provided that the Authority may designate any person employed by the Authority or appointed as such under any written law, as an inspector.

(2) The Registrar shall publish the list of persons appointed or designated as inspectors in the *Gazette*.

(3) The Authority shall provide an inspector with an identification card which shall be prima facie evidence of his appointment.

(4) An inspector shall, in the performance of his functions under this Act,—

(a) bear an identification card referred to under subsection (3); and

(b) on request, show the identification card to any person.

Powers of an
inspector

46.—(1) An inspector may, for the purpose of enforcing this Act, at any reasonable time, without prior notice, and on the authority of a search warrant, enter into any premises that the inspector has reasonable grounds to believe that it is being used by a person licensed or ought to be licensed under this Act to commit an offence or act contrary to the provisions of this Act, and may—

(a) search the premises;

(b) search any person on the premises if there are reasonable grounds to believe that the person has possession of an article or item that has a bearing on the investigation, except that the person shall not be searched by a person of the opposite sex;

(c) take extracts from, or any copies from any book, document or record that is on the premises and that has a bearing on the investigation;

(d) demand the production of relevant certificates and inspect the same; and

(e) make any inquiries as may be necessary in order to ascertain whether this Act or any other written law on which there is an investigation is being complied with.

(2) An inspector shall submit to the Authority, through the Registrar, a written report containing all relevant matters relating to an inspection for the information or action by the Authority, as the case may be.

Non-
compliance
with an
inspector

47. A person who—

(a) delays or obstructs an inspector in the performance of the inspector's duties and functions under this Act;

(b) refuses to give an inspector reasonable assistance as he may require for the purpose of exercising the inspector's functions; or

(c) gives an inspector false or misleading information in response to an inquiry made by the inspector,

commits an offence and shall be liable, upon conviction, to a fine of five million Kwacha and to imprisonment for two years.

PART IX—MISCELLANEOUS

48. Subject to the Constitution, any written law shall not prohibit, restrict or render unlawful, any matter which is done, permitted or authorized in accordance with this Act.

Decriminalization of cannabis

49.—(1) The Authority shall, from time to time, prescribe fees payable for an act specified under this Act.

Fees, cess and levy

(2) The Minister may, by order published in the *Gazette*, prescribe cess, levies and charges at an expressed rate per stated unit of net weight to be paid, levied and collected in respect of—

- (a) cannabis sold in Malawi;
- (b) cannabis exported from Malawi; and
- (c) cannabis imported into Malawi.

50.—(1) Any person who cultivates, propagates, produces, processes, stores, distributes and uses cannabis in contravention of this Act commits an offence and shall, on conviction, be liable to a fine of fifty million Kwacha and to imprisonment for twenty-five years.

Offences

(3) A person who—

(a) without reasonable excuse, refuses to produce any information or documentation when required by the Authority to do so under this Act;

(b) makes any statement knowing it to be false, or provides any information or documentation that is materially incorrect with the intention of misleading the Authority;

(c) without a written permission of the Authority, publishes or discloses to any unauthorized person or otherwise than in the course of duty, the contents of any document, communication or information of any kind which has come to his knowledge in the course of his duty under this Act, commits an offence and shall, upon conviction, be liable to a fine of ten million Kwacha and to imprisonment for five years.

(4) Any person who obstructs or interferes with the Authority, a member, member of staff, inspector, agent or service provider in the performance of any function under this Act or other written law, commits an offence and shall, upon conviction, be liable to a fine of ten million Kwacha and to imprisonment for five years.

51.—(1) Any person, who contravenes the provisions of this Act commits an offence and shall, upon conviction, be liable to a fine of fifty million Kwacha and imprisonment of up to twenty five years.

General and other penalties

(2) Notwithstanding the penalty imposed under subsection (1), —

(a) the court may order that the controlled substance involved in the commission of the offence or violation of the Act under subsection (1), be seized and disposed in such a manner as the court deems fit; and

(b) the Registrar may impose an administrative penalty to any person who contravenes this Act.

Appeals

52.—(1) The Minister shall appoint an Appeals Panel, which shall hear appeals from the decision of the Registrar under this Act.

(2) The Appeals Panel shall comprise—

(a) a retired judge who shall be the chairperson;

(b) an official representing the private sector dealing with cannabis or cannabis products;

(c) a public officer dealing with cannabis or cannabis products; and

(d) an ordinary citizen of good standing and high integrity with knowledge of the cannabis industry:

Provided that where there is equality of votes in the determination of any matter before the Panel, the chairperson shall have, over his deliberative vote, a casting vote.

Experts

(3) The Appeals Panel may appoint any person with special expert knowledge in an advisory capacity in any case where it appears to the committee that such knowledge is required for the proper determination of the case.

Time for
appeals

(4) An appeal shall be brought within thirty days after the date of the decision or order of the Registrar in question.

Legal
representation

(5) In any proceedings before the Appeals Panel, the parties to such proceedings may appear in person or be represented by a legal practitioner.

(6) The Registrar may appear with the leave of the Appeals Panel.

Notifications
by Registrar
to the Appeals
Panel

(7) The Registrar shall notify the Appeals Panel forthwith of any appeal which has been lodged with him against any decision or order.

(8) Where any matter to be decided by the Registrar under this Act appears to him to be of unusual importance or complexity, he may refer that matter to the Appeals Panel for decision.

53. A person who is aggrieved by the decision of the Appeals Panel may apply to the High Court, within thirty days after the date of the decision of the Appeals Panel, for a review of the decision of the Appeals Panel.

Review by
the High
Court

54.—(1) The Authority shall prepare and submit to—

Annual
reports and
reporting

(a) the Minister, within four months after the end of every financial year, a comprehensive annual report on the general conduct of the affairs of the Authority and the activities it has carried out during that financial year;

(b) the National Assembly, through the Minister, within four months after the end of every financial year, a comprehensive annual report on the general conduct of the affairs of the Authority, the activities it carried out during that financial year and the impact of the cannabis on the economy.

(2) The Minister shall lay a copy of every annual report referred to in subsection (1)(a) in Parliament.

(3) The Authority shall, from time to time and in consultation with and through the Minister, apprise the Cabinet, Members of Parliament, Principal Secretaries and Local Government Authorities and Councillors on the work of the Authority and in particular on matters that could affect the cannabis industry.

55.—(1) The Minister may, by notice published in the *Gazette*,—

Powers of the
Minister

(a) on the advice of the Authority, make regulations for the better carrying out of the provisions of this Act; and

(b) amend any Schedule to this Act.

(2) Without prejudice to the generality of subsection (1), the regulations may prescribe—

(a) any matter that may be prescribed under this Act;

(b) the fees or fines payable under this Act;

(c) the appropriate security measures required for cannabis;
or

(d) any matter that the Minister considers necessary or expedient to give effect to the objectives of this Act.

(3) Notwithstanding the provisions of section 21(e) of the General Interpretation Act, the regulations made under this Act may prescribe a penalty of fifty million Kwacha and twenty five years imprisonment.

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SCHEDULE

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OATH OF CONFIDENTIALITY

I,, being a member/having been employed in the service, of the Cannabis Regulatory Authority, do hereby swear/affirm that I will freely without fear or favour, affection or ill will, discharge the functions of a member/an employee, of the Authority, and that I will not directly, or indirectly reveal any matters related to such functions to any unauthorized person or otherwise than in the course of my duty.

SWORN at this day of, 20

Signature:

Before:.....

Commissioner for Oaths

Passed in Parliament this twenty seventh day of February, two thousand and twenty.

FIONA KALEMBA
Clerk of Parliament