REPORT

OF THE

COMMITTEE ON HEALTH, COMMUNITY DEVELOPMENT AND SOCIAL SERVICES

ON THE

CONTROLLED SUSBSTANCES BILL, N.A.B. NO. 2 OF 2023

FOR THE

SECOND SESSION OF THE THIRTEENTH NATIONAL ASSEMBLY

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FOREWORD

Madam Speaker, the Committee on Health, Community Development and Social Services has the honour to present its Report on the Controlled Substances Bill, N.A.B. No. 2 of 2023 referred to it by the House on Tuesday, 28th February, 2023.

The Committee is mandated to consider Bills under Standing Order No 198 (j) of the National Assembly of Zambia Standing Orders, 2021.

In order to acquaint itself with the ramifications of the Bill, the Committee sought both written and oral submissions from different stakeholders and examined in detail all submissions presented to it. The list of witnesses who submitted comments and appeared before the Committee is at Appendix II of this Report. The Committee held nine meetings to consider the Controlled Substances Bill, N.A.B No. 2 of 2023.

The Committee is grateful to all stakeholders who tendered both written and oral submissions. The Committee further wishes to thank you, Madam Speaker, for affording it an opportunity to carry out its work. It also appreciates the services rendered by the Office of the Clerk of the National Assembly and his staff throughout the Committee's deliberations.

Dr Christopher Kalila, MP
CHAIRPERSON

March 2023
LUSAKA

TABLE OF CONTENTS

1.0 MEMBERSHIP OF THE COMMITTEE

The Committee consisted of Dr Christopher Kalila, MP, (Chairperson); Mrs Marjorie Nakaponda, MP (Vice-Chairperson); Mr Miles B E Sampa, MP; Mr Leevan Chibombwe, MP; Dr Aaron Mwanza, MP; Mr Luhamba Mwene, MP; Mr Paul Chala, MP; Mr Heartson Mabeta, MP; Mr Monty Chinkuli, MP; and Mr Joseph S Munsanje, MP.

2.0 BACKGROUND OF THE BILL

The *Dangerous Drugs Act, Chapter 95 of the Laws of Zambia* was enacted in 1967 as the primary legislation on drugs and psychotropic substances in Zambia. The regulatory framework surrounding dangerous drugs and controlled substances was mainly through three statutes namely, the *Dangerous Drugs Act*, the *Narcotic Drugs and Psychotropic Substances Act, No 35 of 2021* and the *Cannabis Act, No 33 of 2021,* which prohibited dealing in narcotic drugs, including cannabis, without lawful authority.

Over time, scientists developed the use of modern synthetic drugs. These drugs which were of great therapeutic value were available as narcotic drugs of opiate-like action (drugs containing opium and used to treat pain) and also in the wider area of psychotropic activity such as central nervous stimulants, sedatives, hypnotics and tranquilisers. The International Opium Commission's attempts to establish an international legal framework for the regulation of psychoactive substances (drugs or other substances that affected the nervous system and caused changes in mood, awareness, thoughts, feelings, or behaviour) had culminated in a number of international treaties. In this regard, the legal framework governing dangerous drugs and controlled substances in Zambia was archaic and there was need to bring the law into conformity with international best practices.

In view of the foregoing, the Government introduced the Controlled Substances Bill, N.A.B No. 2 of 2023to, among others, provide for procedures and criteria for classification of controlled substances and provide for the functions of the Zambia Medicines Regulatory Authority in relation to controlled substances.

3.0 OBJECTS OF THE BILL

The objects of this Bill were to-

(a) provide for the granting of a licence to deal in, manufacture, import and export of a controlled substance;
(b) regulate the use, dispensing, manufacture, wholesale, transfer, supply, sell, distribution and possession of a controlled substance for medicinal, scientific and research purposes;

(c) provide for procedures and criteria for classification of controlled substances;
(d) provide for the functions of the Zambia Medicines Regulatory Authority relating to controlled substances;
(e) repeal and replace the Dangerous Drugs Act, 1967; and
(f) provide for matters connected with, or incidental to, the foregoing.

4.0 SALIENT PROVISIONS OF THE BILL

The salient provisions of the Controlled Substances Bill, N.A.B No. 2 of 2023, were as set out hereunder.

PART I - PRELIMINARY PROVISIONS

Clauses 1 and 2 – Short Title, Commencement and Interpretation

The clauses provided the citation of the Act, once enacted, and the date on which the Act would come into operation. The clauses also provided the definitions of key words and phrases used in the Bill in order to make the law easier to understand by the citizens and those tasked to implement the law.

PART II - ADMINISTRATION

Clause 3 and 4 – Administration and Functions of the Authority

The clauses placed the mandate of administering the Act on the Zambia Medicines Regulatory Authority (herein after referred to as the Authority) and also provided for its functions to ensure proper administration of the Act. Clause 4 further, provided for the functions of the Authority.

PART III – LICENSING FOR CONTROLLED SUBSTANCES

Clause 5 – Non-application of Part III

The clause exempted the controlled substances listed in the Sixth Schedule from the licensing requirements under the Act. The clause further set out the manner in which the controlled substances in the Sixth Schedule would be regulated.

Clause 6 - Prohibition of Manufacturing, Importing, Exporting, Dealing in or Advertising of Controlled Substances

The clause sought to prohibit a person from manufacturing, importing, exporting, dealing in or advertising a controlled substance without a licence issued by the Authority, and provided a sanction for a person found guilty of such an offence.

Clause 7 – Application for Licence

The clause mandated a person who intended to manufacture, import, export, and deal in or advertise a controlled substance to apply to the Authority for a licence. The clause further set out the procedure for the consideration of an application by the Authority and the validity period of a licence.

Clauses 8, 9, 10, 11, 12 and 13 – Renewal, Revocation, Amendment and Transfer of Licence

These clauses provided for among others, the renewal of licences, suspension or revocation of the licence where a licensee was in breach of the licence conditions and granted power to the Authority to amend a licence within fourteen days.

The provisions also mandated a licensee to submit to the Authority quarterly returns on a controlled substance not later than fourteen days of the next quarter. The provisions further sanctioned a licensee who failed to submit a quarterly return within the prescribed period.

Further, a licensee was prohibited from transferring a licence to a third party without prior authorisation of the Authority. In addition, the provisions set out the manner in which the aforementioned authorisation could be obtained, and the procedure for the consideration of the application by the Authority.

PART IV - MANUFACTURING, SUPPLY, DISTRIBUTION, SELLING, USING, PRESCRIBING AND DISPENSING OF CONTROLLED SUBSTANCES

Clause 14 – National Annual Requirements for Controlled Substances

The clause mandated the Authority to determine the total quantity, and establish the national annual requirements for each class of a controlled substance for different purposes.

Clause 15 – Prohibition of Placing on Market etc., Controlled Substance Used as Medicine without Pharmaceutical Licence

The clause prohibited a person from placing on the market, advertising, promoting, manufacturing, selling, importing, supplying or dealing with a controlled substance used as a medicine without a pharmaceutical licence issued by the Authority in accordance with the *Medicines and Allied Substances Act, No. 3 of 2013*.

Clause 16 – Application for Pharmaceutical Licence

The clause obliged a person who intended to place on the market, advertise, promote, manufacture, sell, import, supply or deal in a controlled substance used as a medicine to apply to the Authority for a pharmaceutical licence in accordance with the *Medicines and Allied Substances Act, No. 3 of 2013*.

Clause 17 – Authorisation for Certain Classes of Persons

The clause set out the classes of persons that were authorised for the practice or exercise of that person's profession, function or employment to be in possession of, dispose, use, prescribe or dispense, a controlled substance. These persons included, among others, a health practitioner and a veterinary surgeon. The clause further set out the standard of care by such persons of the controlled substance.

Clause 18 – Prescribing or Dispensing Controlled Substances

The clause permitted an authorised prescriber to prescribe, and an authorised dispenser to dispense, a controlled substance for treatment in accordance with guidelines issued by the Authority.

Clause 19 – Withdrawal and Restoration of Authorisation

The clause permitted the Authority, by notice in the Gazette, to revoke the authorisation of any person under clause 16 where that person, among others –

a. committed an offence under the Act, or attempted to solicit, incite, aid or abet, any other person to commit any offence under the Act; or
b. had that person's licence or certificate of practice suspended or revoked.

Clauses 20, 21 and 22 -Prescription

The clauses prohibited a person from selling or supplying a controlled substance which required a prescription, without a prescription. However, the clauses permitted the sell and supply of controlled substances for medicinal purposes on partial filling of a prescription for a controlled substance set out in the First, Second, Third, Fourth and Fifth Schedules. It further set out the conditions upon which the permission may apply.

Clause 22 permitted an authorised seller of a controlled substance to sell or supply a controlled substance without a prescription, where the authorised seller was reasonably satisfied that the person requesting a controlled substance was an authorised prescriber and by reason of some emergency the authorised prescriber was unable to furnish a prescription immediately.

The clause further mandated the authorised prescriber to furnish the authorised seller with a prescription within seven days of the delivery of a controlled substance, and sanctioned an authorised prescriber who failed to provide the prescription with the specified period.

Clause 23- Retail of Precursors and Listed Chemicals

The clause mandated a retailer to ensure that the sale of a product containing precursor chemicals or other chemicals set out in the Fifth Schedule was made in accordance within the guidelines issued by the Authority.

Clause 24 - Consignment of Controlled Substance in Transit

The clause placed a duty on exporters to notify the Authority, the Drug Enforcement Commission and Zambia Revenue Authority where a controlled substance was permitted under the law of any foreign country to be exported to another country, and was transited through the Republic as provided in the Customs and Excise Act. The clause further prohibited the exporter from causing, or procuring the controlled substance to be diverted to any destination within the Republic without authorisation and sanctioned an exporter who did not comply.

Clause 25 - Prohibition of Diversion of Controlled Substances within Republic

The clause prohibited a person, without authorisation, from causing a controlled substance to be diverted to a destination within the Republic, other than the destination to which it was originally assigned and sanctioned a person who did not comply.

Clause 26 - Use of Controlled Substances in Health Research

The clause mandated a person who intended to carry out health research on a controlled substance set out in the First, Second, Third, Fourth, Fifth and Sixth Schedules to do so in accordance with the *National Health Research Act, No 2 of 2013*and the Medicines and Allied Substances Act, *No. 3 of* 2013.

The clause further mandated the Authority and the National Health Research Authority to ensure effective procedures to adequately safeguard against diversion of a controlled substance from legitimate medicinal, scientific or research purposes in setting the criteria for assessing the merits of a research protocol using a controlled substance. The clause further set out the factors that the Authority and the National Health Research Authority should take into consideration when setting the criteria.

PART V - CLASSIFICATION AND EXEMPTION OF CONTROLLED SUBSTANCES

Clause 27- Classification of Controlled Substances

The clause empowered the Minister, by statutory instrument and on the recommendation of the Authority, to classify a controlled substance in the First, Second, Third, Fourth, Fifth and Sixth Schedule. The clause further mandated the

Authority, when making a recommendation under subsection (1), to ensure that the classification was done in accordance with specified levels of potential abuse.

Clause 28 - Exemptions for Certain Purposes

The clause set out exemptions of a controlled substance from certain provisions of the Act on certain conditions being met, such as, the controlled substance not having a significant potential for abuse, or the compound, mixture or preparation containing a controlled substance which was not for administration to a human being or animal. The clause further empowered the Minister to revoke an exemption of a controlled substance by statutory instrument on consideration of specific factors. It further prohibited a person from diverting a controlled substance without authorisation from the Authority and provided for sanctioning of a person who did so.

Clause 29 - Non-prescription Preparation Containing Controlled Substance

The clause empowered the Minister, subject to the *Medicines and Allied Substances Act, No. 3 of 2013,* to exempt by statutory instrument a preparation containing a controlled substance from the application of the Act, if the preparation containing a controlled substance may be sold over the counter without a prescription.

Clause 30 - Temporary Classification of Controlled Substance to Avoid Imminent Hazards to Public Safety

The clause empowered the Minister, on the recommendation of the Authority, by statutory instrument, to order the temporal classification of a controlled substance to avoid an imminent hazard to the public. The clause further empowered the Minister, on the recommendation of the Authority, by statutory instrument, to remove a controlled substance from a schedule on a temporary basis, where the reasons advanced for the grant of the temporary classification ceased to exist.

Clause 31 - Temporary and Permanent Classification of Anabolic Steroids

The clause empowered the Minister, on the recommendation of the Authority, by statutory instrument, to order the temporal classification of an anabolic steroid as a controlled substance if the Authority found that such classification would assist in preventing abuse or misuse of the anabolic steroid. The clause further empowered the Minister, on the recommendation of the Authority, by statutory instrument, to remove an anabolic steroid from a schedule on a temporary basis, where the reasons advanced for the grant of the temporary classification ceased to exist.

Lastly, the clause empowered the Minister, on the recommendation of the Authority, by statutory instrument, to permanently include an anabolic steroid as a controlled substance in the appropriate schedule.

PART VI - REPORTS, RECORDS, INVENTORIES AND REGISTERS

Clause 32- Records or Inventory of Licensed Activity

The clause mandated a licensee to establish and maintain a complete and accurate record or inventory of each controlled substance that was manufactured, imported, advertised or dealt in.

The clause further placed a duty, among others, on a higher education institution, research institution and registered business entity to which a person in charge of a laboratory which was used for the purpose of research or education was attached to establish and maintain a complete and accurate record or inventory of each controlled substance.

Lastly, the clause provided for the sanctioning a person or institution that did not comply with its provisions.

Clause 33 - Registers by Other Person or Institution

The clause placed a duty on a person or institution, other than a person or institution provided for under clause 32, in possession of a controlled substance for purposes of disposal, use, prescribing or dispensing to keep and maintain a register of controlled substances. The clause further provided for the sanctioning of a person or institution that contravened its provisions.

Clause 34 - Preservation of Documents

The clause mandated a licensee, health facility, animal health facility, higher education institution, research institution, registered business entity, or other person or institution to preserve registers, records, inventories, books, prescriptions, orders in writing or other documents issued or made for the purposes of the Act for a period of five years from the date on which the last entry was made or issued. The clause further provided for the sanctioning of the aforementioned persons or institutions who did not comply with the requirement.

PART VII - INSPECTIONS

Clause 35 -Power of Authorised Officer

The clause empowered an authorised officer for purposes of enforcing the provisions of the Act, once enacted, with a warrant at any reasonable time to, among others:

a. enter any premises, pharmacy, agro veterinary shop, container, vessel, vehicle, aircraft or other conveyance that the authorised officer had

reasonable grounds to believe was used for the commission of an offence or for purposes contrary to the provisions of the Act; and

b. search any premises where any activity in relation to controlled substances is being undertaken, including a pharmacy, agro veterinary shop, container, vessel, vehicle, aircraft or other conveyance, or the premises of a manufacturer, importer, exporter or dealer of any controlled substances or a person licensed or regulated under the Act, including a private dwelling, where information or documents which may be relevant to an inspection may be kept or which were being used for the commission of an offence under the Act.

Clause 36 - Powers of Arrest

The clause permitted an authorised officer to arrest a person without a warrant in circumstances where that person, among others:

a. was committing or had committed an offence under the Act; or
b. was about to commit an offence under the Act and there was no other way to prevent the commission of the offence.

PART VIII - OFFENCES AND PENALTIES

Clause 37 - Maintaining Controlled Substance Involved Premises

The clause provided for offences relating to, among others, the maintenance, management or control of a place, whether temporarily or permanently for the purpose of unlawfully manufacturing, storing, distributing or using a controlled substance. The clause further provided for the sanctioning of a person found guilty of an offence under the clause.

Clause 38 - Sale of Controlled Substances to Children

The clause provided for the sanctioning of a person who dealt in a controlled substance with a child.

Clause 39 - Employing, Hiring, Using, Persuading, Inducing, Enticing or Coercing Children to Distribute Drugs

The clause provided for the sanctioning of a person who knowingly employed, hired, used, persuaded, induced, enticed or coerced a child to contravene the Act or a person who employed, hired, used, persuaded, induced, enticed or coerced a child to assist in avoiding detection or apprehension for an offence under the Act.

Clause 40d - Prohibition of Possession of Controlled Substance

The clause prohibited a person from possessing a controlled substance without authorisation under the Act or any other written law, and provided a penalty

where the clause was contravened. The clause further excluded the application of the provision where an appropriate authority was procuring the controlled substance in accordance with the requirements of any written law.

Clause 41 - Offence of Import, Export, Manufacture, Possession and Use of Prepared Opium

The clause mandated a person who intended to import, export, manufacture or use prepared opium to apply for authorisation from the Authority. The clause further set out offences relating to prepared opium and the corresponding penalty for failure to comply with the provision.

Clause 42d - General Penalty

The clause provided a general penalty for offences under the Act for which a specific penalty was not provided.

Clause 43 - Offences by Principal Officer, Shareholder or Partner of Body Corporate or Unincorporate body

The clause sought to hold a director, manager, shareholder or partner of a body corporate or unincorporate body liable for offences committed by that body corporate or unincorporate body under specified circumstances.

PART IX - GENERAL PROVISIONS

Clause 44 - Waiver by Authority

The clause permitted the Authority to waive certain requirements under the Act for the purposes of importation or exportation of a controlled substance where a national global disaster or health emergency was declared.

Clause 45 - Appeals

The clause set out the appeals procedure for decisions made under the Act.

Clause 46 - Disposal of Controlled Substances

The clause mandated the Authority to dispose of expired, obsolete or unwanted controlled substances in collaboration with the Zambia Environmental Management Agency and any other appropriate authority.

Clause 47 - Requirements in Respect of Cessation of Practice

The clause set out the actions to be taken by a person in lawful possession of a controlled substance before that person ceased to practice in a profession or be in employment. The clause further permitted the Authority to determine, in consultation with the Zambia Environmental Management Agency, the manner in

which the controlled substances would be disposed of where arrangements were not made or were not to the satisfaction of the Authority in accordance with sub-clause (1) (b).

Clause 48 - Forfeiture

The clause required a person convicted of an offence under the Act, to forfeit to the Republic all articles in respect of which the offence was committed. The clause further empowered the court before which the person was convicted to order the destruction or disposal of articles in respect of which the offence was committed as the court deemed fit at the convicted person's cost.

Clause 49 - Guidelines

The clause empowered the Authority to issue guidelines which were necessary for the better carrying out of the provisions of the Act. The clause further mandated the Authority to publish the guidelines in the Gazette or any other electronic media to be determined by the Authority.

Clause 50 - Power of Minister to Amend Schedules

The clause empowered the Minister, by statutory instrument, on the recommendation of the Authority and in consultation with the Drug Enforcement Commission to amend the schedules under specified circumstances. The clause further set out the factors that the Minister ought to take into account when amending a schedule.

Clause 51 -Regulations

The clause empowered the Minister to make regulations for the better carrying out of the provisions of the Act and for anything required to be prescribed under the Act.

Clause 52 -Repeal of Act No. 42 of 1967 and Savings and Transitional Provisions

The clause sought to repeal the Dangerous Drugs Act, 1967, and set out the savings and transitional provisions once the Act was operationalised.

8. CONCERNS BY STAKEHOLDERS

Stakeholders who appeared before the Committee supported the Bill. They, however, raised concerns as outlined below.

i. Clause 2

Stakeholders submitted that the restriction of definition of health practitioners as *"a medical doctor, medical licentiate, pharmacist, dental*

surgeon or another person as the Minister may, on the advice of the Authority, by statutory instrument, designate" was limiting in the context of the *Health Professions Act, No. 24 of 2009* and the scope of practice which defined and limited the practice of registered health practitioners.

Various other health practitioners, including clinical psychologists, clinical officers-anaesthetists and clinical officers-psychiatry, prescribed and administered controlled medicines as guided under their scope of practice as regulated by the Health Professions Council of Zambia, using established clinical protocols. Some stakeholders were, therefore, of the view that the definition be amended to read *"health practitioner has the meaning assigned under the Health Professions Act, No. 24 of 2009."*

Further, inclusion of the following definitions was proposed by some stakeholders:

a. *"public health" has the meaning assigned to it under the Zambia National Public Health Institute Act; and*
b. *"Council" has the meaning assigned to it under Health Professions Act, 2009.*

Some stakeholders further expressed concern that the Bill had omitted 'Police Officer' from the definition of authorised officer. They therefore, proposed that 'police officer' be included in the definition of authorised officer, as police officers have representation across the country including far-flung areas.

Subsequently, clause 36 (2) should be amended to read *"an authorised officer other than a police officer shall, where the authorised officer arrests a person under subsection (1), handover the person to a police officer, or surrender that person to a police post or station within twenty four hours of the arrest."*

Some stakeholders expressed concern that the definition of the term "medicinal purposes" which was defined as "*use of a controlled substance for the treatment or prevention of a disease or for some other definite curative or therapeutic purpose, but excludes the satisfaction or relief of a habit or craving for the controlled substances"* excluded the use of medications like Methadone or Buprenorphine or Naltrexone for the relief of craving, which was the target during treatment of patients with substance use disorders.

It was therefore, proposed that the last part of the definition which reads "*but excludes the satisfaction or relief of a habit or craving for the controlled substances"* should be deleted or amend the definition to read "*use of a controlled substance for the treatment or prevention of a disease or for some other definite curative or therapeutic purpose, but exclude the diversion of these controlled substances for non medicinal purposes."*

ii. Clause 7 – Application for Licence

Stakeholders submitted that there may be confusion in the implementation of clause 7(2) which compelled the Authority to approve or reject an application for a licence to manufacture a controlled substance within thirty days as provided under clause 7(1) and section 34(2) of the *Medicines and Allied Substances Act No. 3 of 2013.* The Act required the Authority to make a decision within ninety days especially for a start-up manufacturing site or facility. Clause 15 (1) of the Bill also made reference to the Act where it required a person to also comply with the Act even in the case of manufacturing.

Stakeholders were, therefore, of the view that the timeframe stated in clause 7(2) of the Bill be harmonised with that of section (2) of the Act.

iii. Clause 17 – Authorisation for Certain Classes of Persons

Some stakeholders submitted that clause 17(2) which reads *"A person referred to under subsection (1) who is in possession of a medicine containing a controlled substance, shall, except when required by the practice of a profession, function or employment, keep the medicine in a locked immovable receptacle which shall be opened only by that person or another person authorised by virtue of this section, to be in possession of a controlled substance."* should be amended to read:

> *"A person referred to under subsection (1) who is in possession of a medicine containing a controlled substance, shall, except when required by the practice of a profession, function or employment, keep the medicine in a locked immovable receptacle which shall be opened only by that person or another person in the presence of a witness authorised by virtue of this section, to be in possession of a controlled substance."*

iv. Clause 27 – Classification of Controlled Substances

Stakeholders submitted that the definition of "controlled substances" included a term "other chemical" which had no interpretation in the Bill for clarity.

In this regard, stakeholders where of the view that the controlled substance definition should exclude the term "other chemical" as it was not consistent with that of the *Narcotic Drugs and Psychotropic Substances Act No. 35 of 2021*, wherein the precursor chemical terminology was defined.

The exclusion of the words "other chemical" should be considered for deletion wherever it appeared in the proposed Bill specifically under clauses 27 (2)(e) and 50(2)(h).

v. Some stakeholders expressed concern that the proposed sixth schedule had a limited number of substances which were essential chemicals used as

reagents and solvents in the manufacturing process of illicit drugs. It was therefore, proposed that the sixth schedule be expanded to cater for other essential chemicals not listed in the schedule and these should include among others, hydriodic acid, hydrogen chloride gas, hypophosphorous acid, iodine, phosphorous (red or yellow), phosphorous (red), sodium permanganate.

9.0 COMMITTEE'S OBSERVATIONS AND RECOMMENDATIONS

i. Clause 2 – Preliminary Provisions

The Committee in acknowledging the concerns of the stakeholders recommends that the definition of health practitioner in the Bill should have the meaning as assigned under the *Health Professions Act, No. 24 of 2009*, so as not to restrict the health practitioners to only those listed in the definition of the proposed Bill.

Further, the Committee recommends that 'police officer' be included in the definition of authorised officer and subsequently recommend for the amendment of clause 36 (2) as follows:

> *"an authorised officer other than a police officer shall, where the authorised officer arrests a person under subsection (1), handover the person to a police officer, or surrender that person to a police post or station within twenty four hours of the arrest."*

The Committee in agreeing with the submission by some stakeholders recommends that the definition of the term "medicinal purposes" be amended to either read:

> "*use of a controlled substance for the treatment or prevention of a disease or for some other definite curative or therapeutic purpose,* **or**
> "*use of a controlled substance for the treatment or prevention of a disease or for some other definite curative or therapeutic purpose, but exclude the diversion of these controlled substances for non medicinal purposes."*

So as to provide for health practitioners who use controlled substances such as methadone, buprenorphine and naltrexone for the treatment of opioid use disorder for the relief of craving which is the target during the treatment of patients with substance use disorder.

ii. Clause 7 – Application for Licence

The Committee in agreeing with stakeholders recommends that the timeframe stated in clause 7(2) of the Bill be harmonised with that of section 34(2) of the *Medicines and Allied Substances Act No. 3 of 2013,* considering that the Act is being referred to in the Bill. In this regard, confusion would be

avoided in the implementation of the two laws especially for start-up manufacturing sites or facilities.

iii. Clause 17 – Authorisation for Certain Classes of Persons

The Committee supports the proposal by some stakeholders and recommends that clause 17(2) be amended to read:

> *"A person referred to under subsection (1) who is in possession of a medicine containing a controlled substance, shall, except when required by the practice of a profession, function or employment, keep the medicine in a locked immovable receptacle which shall be opened only by that person or another person* ***in the presence of a witness*** *authorised by virtue of this section, to be in possession of a controlled substance."*

iv. Clause 19 – Withdrawal and Restoration of Authorisation

The Committee observes with concern that other categories of health practitioners, such as Clinical Officer Psychiatry and Clinical Psychologists who diagnose drug addictions using established clinical protocols as regulated by the HPCZ were not covered under clause (19) (1) (d).

In this regard, the Committee recommends that clause (19)(1)(d) be amended by deleting the words "medical doctor" and replacing it with the words "health practitioners."

v. Clause 27 – Classification of Controlled Substances

The Committee expresses concern that the definition of "controlled substances" includes a term "other chemical" which has no interpretation in the Bill for clarity.

In this regard, the Committee recommends that the controlled substance definition should exclude the term "other chemical" as it was not consistent with that of the *Narcotic Drugs and Psychotropic Substances Act No. 35 of 2021,* wherein the precursor chemical terminology was defined.

The Committee is, therefore, of the view that the words "other chemical" should be deleted wherever they appeared in the proposed Bill, specifically under clauses 27 (2)(e) and 50(2)(h).

vi. The Committee further recommends that essential chemicals used as reagents and solvents hydriodic acid, hydrogen chloride gas, hypophosphorous acid, iodine, phosphorous (red or yellow), phosphorous (red), sodium permanganate in the manufacturing process of illicit drugs, should be included in the sixth schedule as leaving them out would pose a challenge in monitoring the said chemicals in their use to prevent or curb trafficking and diversion

including prosecution of the offenders in line with the provisions of the Bill.

10.0 GENERAL COMMITTEE'S OBSERVATIONS AND RECOMMENDATIONS

The Committee notes with concern that a number of substances and drugs being abused locally by mostly the youths were not part of the drugs in the schedules provided for in the Bill. The Committee is, therefore, of the view that a comprehensive investigation of substances and drugs, among others glue; Gentamycin eye drops; Methylated spirit; Volo (heroin mixed with teething powder); Shisha; Nsunko; blue mash (promethazine tablets) be carried out so that they can either be provided for in their own schedule or should fall under adulterants.

Further, the Committee recommends that regulation should be strengthened on the sale of prescription medicines such as among others, ARVs (Efferenz); and cough mixtures and tablets containing codeine being abused.

11.0 CONCLUSION

The Committee notes that the enactment of the Controlled Substances Bill, 2023, is progressive as it aims at ensuring availability of controlled substances for medicinal, research and scientific purposes. Further, the enactment of the Bill will help in the prevention of both trafficking and diversion of controlled substances.

We have the honour to be, Madam Speaker, the Committee on Health, Community Development and Social Services mandated to consider the Controlled Substances Bill N.A.B No. 2 of 2023.

Dr Christopher Kalila, MP
CHAIRPERSON

March, 2023
LUSAKA

APPENDIX I – List of National Assembly Officials

Mr Francis Nabulyato, Principal Clerk of Committees (SC)
Mrs Chitalu K Mumba, Deputy Principal Clerk of Committees (SC)
Mrs Angela M Banda, Senior Committee Clerk (SC)
Mrs Media H Mweele, Committee Clerk
Ms Luyando Chilala, Administrative Assistant
Mr Muyembi Kantumoyo, Parliamentary Messenger

APPENDIX II – LIST OF WITNESSES

Ministry of Justice
Minister of Health
Ministry of Health
Chainama Hills College
Drug Enforcement Commission
Health Professions Council of Zambia
National Health Research Authority
Pharmaceutical Society of Zambia
University of Zambia
Zambia Revenue Authority
Zambia Association of Manufacturers
Zambia Police Service
Zambia Medical Regulatory Authority
Zambia Medical Associations