



REPUBLIC OF ZAMBIA

REPORT

OF THE

**COMMITTEE ON HEALTH, COMMUNITY DEVELOPMENT AND SOCIAL
SERVICES**

ON THE

**MEDICINES AND ALLIED SUBSTANCES (AMENDMENT) BILL N.A.B NO. 51
OF 2026**

FOR THE

FIFTH SESSION OF THE THIRTEENTH NATIONAL ASSEMBLY

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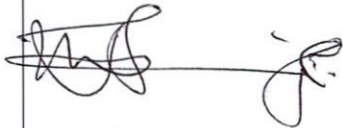
FOREWORD

Honourable Madam Speaker, the Committee on Health, Community Development and Social Services has the honour to present its Report on the Medicines and Allied Substances (Amendment) Bill N.A.B No. 51 of 2026, for the Fifth Session of the Thirteenth National Assembly.

The Committee is mandated to consider Bills referred to it by the House pursuant to Standing Orders 112(3) and 207(j) of the National Assembly Standing Orders, 2024.

In order to acquaint itself with the ramifications of the Bill, the Committee sought both written and oral submissions from selected stakeholders. The Report highlights the background, objectives and provisions of the Bill, stakeholder submissions, and the Committee's observations and recommendations.

The Committee is indebted to all stakeholders who made submissions and expresses gratitude to you, Madam Speaker, for the opportunity to scrutinise the Bill. Appreciation is also extended to the Office of the Clerk for the support rendered.



Mr Joseph S Munsanje, MP
CHAIRPERSON

May, 2026
LUSAKA

1.0. COMPOSITION OF THE COMMITTEE

The Committee consisted of Mr Joseph S Munsanje, MP (Chairperson); Mrs Marjorie Nakaponda, MP (Vice Chairperson); Dr Christopher K Kalila, MP; Mr Paul Chala, MP; Mr Monty Chinkuli, MP; Mr Heartson Mabeta, MP; Mr Leevan Chibombwe, MP; Mr Masautso Tembo, MP; Mr Miles Sampa, MP and Mr Elias Mubanga, MP.

2.0. BACKGROUND

The Medicines and Allied Substances Act No. 3 of 2013, establishes the Zambia Medicines Regulatory Authority (ZAMRA) as the statutory body mandated to regulate medicines and allied substances in Zambia in order to ensure their quality, safety, and efficacy.

The Government, through the Medicines and Allied Substances (Amendment) Bill N.A.B No. 51 of 2026 proposes to amend the principal Act to revise, among others, the composition of the Board and related governance provisions. This revision is part of the broader public sector reform programme guided by Cabinet Office Circular Minute No. CO.101/39/1 of 2025. The Circular directs all Ministries to streamline Boards and Committees of State-Owned Enterprises (SOEs) in order to strengthen governance, enhance representation and service delivery. It specifically requires that Boards and Committees include private sector representation, not to exceed eleven members, ensure gender balance, and reflect national diversity.

The reforms aim at strengthening institutional governance by promoting accountability, transparency, operational efficiency, and long-term sustainability. This approach is aligned with domestic and internationally recognised best practice stipulated in the National Corporate Governance Code and the Organisation for Economic Co-operation and Development Guidelines on Corporate Governance of State-Owned Enterprises (2015). Accordingly, the proposed amendments in the Bill seek to align the composition of the ZAMRA Board with these established governance principles.

3.0. OBJECT OF THE BILL

The object of this Bill is to amend the Medicines and Allied Substances Act No. 3 of 2013 so as to:

- i. revise the composition of the Board of the Zambia Medicines and Medical Supplies Agency; and
- ii. provide for matters connected with, or incidental to, the foregoing.

4.0. SALIENT PROVISIONS OF THE BILL

Clause 3: Amendment of Section 7 – Composition of the Board

This clause revises the composition of the Board of the Agency by replacing the existing provisions with a new structure comprising part-time members including ministries responsible for health and finance, the Attorney-General's Chambers, professional bodies, and the private sector.

The clause further introduces a requirement for ministries, institutions, and organisations to nominate their representatives for appointment by the Minister, thereby enhancing transparency in the appointment process.

5.0. SUBMISSIONS FROM STAKEHOLDERS

Stakeholders submitted various views on the clauses of the Bill, which are outlined below:

5.1. Clause 3: Amendment of section 7, Composition of the Council

Stakeholders submitted that the Principal Act establishes a fifteen (15) member, technically specialised Board, while the Bill proposed an eleven (11) member Board, comprising of representatives from selected ministries and introducing broader stakeholder representation, thereby streamlining the Board structure but reducing specialised professional representation. They specifically highlighted the following:

i. Removal of technical and professional representation

Stakeholders strongly objected to the removal of key technical stakeholders, including representatives from academia, pharmaceutical, and veterinary professions. It was submitted that medicines regulation inherently requires scientific and professional expertise in areas such as safety, quality, and efficacy assessment. Therefore, the exclusion of these groupings was viewed as a fundamental departure from established regulatory principles and was said to undermine technical decision-making, weaken professional oversight, and reduce the Board's ability to effectively regulate medicines.

ii. Inclusion of non-technical stakeholders and dilution of expertise

Stakeholders observed that the inclusion of farmers' organisations, biodiversity and agro-economy representatives, and three (3) non-governmental organisations engaged in biodiversity broadened the Board's composition but rendered it largely non-technical. While acknowledging their relevance in wider development contexts, they submitted that their prominence within a medicines regulatory Board risked diluting technical expertise and shifting the Authority towards counter-regulatory interests of ZAMRA. They further observed that clause 3(1)(f) was overly broad and overlapped with clause 3(1)(c) and (g). Stakeholders cautioned that this imbalance could weaken regulatory credibility and expose the Board to policy capture by interest groups.

In this regard, stakeholders recommended the revising of clause 3(1)(c) and (g) to include:

- i. a dean from a recognised higher learning institution actively engaged in medicines and allied substances;
- ii. a representative from the Pharmaceutical Society of Zambia;
- iii. a representative from the Veterinary Association of Zambia; and
- iv. a representative from the private sector with distinguished knowledge and experience in pharmaceutical vigilance.

iii. **Inclusion of the Attorney General**

Stakeholders submitted that the inclusion of a representative of the Attorney-General should not be mandatory. They argued that the Service already has a fully-fledged legal department capable of handling legal matters and, where necessary, the Board could seek guidance from the Ministry responsible for health or the Attorney-General's Chambers. In this regard, making such representation a prerequisite may be redundant and could overstretch the Auditor General's office.

iv. **Inconsistency with international best practices**

Stakeholders submitted that international standards, including African Union Model Law principles and world Health Organisation global medicines regulation frameworks, emphasise competence-based appointments and strong technical representation. However, stakeholders observed that the proposed amendments do not adequately align with these principles, particularly due to the reduction of technical expertise and increased reliance on non-specialist stakeholders.

5.2. Clause 2: Nomination and appointment of Board members

i. **Need for competence-based and transparent appointments**

Stakeholders emphasised that appointments must be based on competence, relevant expertise, and professional qualifications. Additionally, stakeholders emphasised the importance of transparent, merit-based appointment processes to enhance governance integrity. They observed that the existing nomination framework may allow the appointment of junior officers, potentially undermining the quality, timeliness, and strategic depth of decision-making. They further noted that the proposed nomination approach does not sufficiently ensure gender considerations due to its fragmented structure. Accordingly, they supported the introduction of clear criteria, standards, and safeguards to ensure that appointments are competence-based, inclusive, and aligned with the Authority's mandate.

6.0. COMMITTEE'S OBSERVATIONS AND RECOMMENDATIONS

After carefully studying submissions from stakeholders, the Committee makes the following observations and recommendations:

Retention of technical and professional representation

- 6.1. The Committee observes that the exclusion of academia, pharmaceutical, and veterinary professionals undermines technical oversight. In light of this, the Committee recommends reinstating key technical representatives, including academia, the Pharmaceutical Society of Zambia, and the Veterinary Association of Zambia as proposed in 5(1)(ii) above.

Exclusion of the Attorney-General

- 6.2. The Committee observes that mandatory inclusion of the Attorney-General's representative may be redundant given existing internal legal capacity. The Committee, therefore, recommends making such representation optional or on a needs basis to avoid duplication and inefficiency.

To this effect, the Committee recommends that the Board should comprise the following:

No	Board Representative (s)
i.	one representative each of the Ministries responsible for- (i) health; (ii) animal health; and (iii) commerce.
ii.	a dean from a recognised higher learning institution actively engaged in medicines and allied substances
iii.	a representative of the Health Professions Council of Zambia
iv.	a representative of the Pharmaceutical Society of Zambia
v.	a representative of the Veterinary Association of Zambia
vi.	a representative of the Zambia Medical Association
vii.	a representative from the private sector with distinguished knowledge and experience in pharmaceutical vigilance

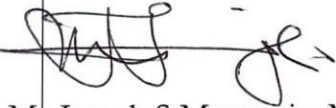
Nomination and appointment framework

- 6.3. The Committee notes that the current nomination framework lacks clarity and may permit the appointment of junior or unqualified officers, while also failing to guarantee gender balance and other inclusive considerations. Therefore, the Committee recommends establishing clear eligibility criteria, transparent nomination procedures, and enforceable gender and other relevant inclusivity provisions to ensure merit-based and balanced appointments. The criteria will ensure:

- i. a structured nomination process for institutions, supported by clear criteria to ensure competence, transparency, and credibility;
- ii. nominations are align with Article 259 (b) and (c) of the Constitution of Zambia regarding gender and youth considerations;
- iii. institutions are compelled to nominate senior qualified officials to the Board to enhance effective participation, expedite decision-making, and strengthen strategic oversight; and
- iv. safeguards that protect the Authority's autonomy, including conflict-of-interest provisions and limits on undue external influence, to preserve its credibility and effectiveness.

7.0. CONCLUSION

The Committee acknowledged the intention of the Bill to reform the governance of the Zambia Medicines Regulatory Authority. However, they raised concerns regarding the removal of critical technical and professional representation, overrepresentation of non-technical stakeholders, nomination criteria and potential risks to regulatory independence. The proposed composition may weaken scientific decision-making and undermine public health protection. In view of this, the Committee urges that the Bill be revised to ensure a balanced, a competence-based Board aligned with the Authority's technical mandate and international best practices.



Mr Joseph S Munsanje, MP
CHAIRPERSON

May, 2026
LUSAKA

APPENDIX I - NATIONAL ASSEMBLY OFFICIALS

Mr Charles Haambote, Director (Social Committees)

Mrs Chitalu K Mumba, Deputy Director (Social Committees)

Mr Darius Kunda, Senior Committee Clerk (SC1)

Mr Kelezo Lushako, Committee Clerk

Ms Catherine Chibuye, Administrative Assistant II

Mr Daniel Lupiya, Senior Committee Assistant

Mr Muyembi S Kantumoya, Committee Assistant

Ms TaonaChabinga, Committee Assistant

APPENDIX II–LIST OF WITNESSES

Institute of Directors Zambia

Ministry of Health

Ministry of Justice

Pharmaceutical Society of Zambia

Zambia Medical Association

Zambia Medicines and Regulatory Agency

Zambia Institute for Policy Analysis and Research

Veterinary Association of Zambia