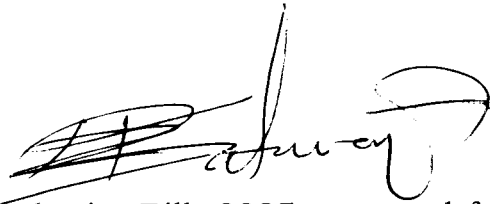


1.0 Introduction

Rt. Hon. Speaker and Hon. Colleagues,



The National Drug and Health Products Authority Bill, 2025 was read for the first time on 4th September, 2025 by the Minister of State for Health, Hon. Anifa Kawooya. In accordance with Rule 135(1) of the Rules of Procedure of Parliament, the Rt. Hon. Speaker referred the Bill to the Sectoral Committee on Health for consideration.

The Committee proceeded to handle the Bill according to Rule 135 (2), (3) and (4) by examining the Bill in detail and made all such inquiries, received and scrutinized proposed amendments that were relevant to the subject matter of the Bill.

2.0 Background

The National Drug and Health Products Authority Bill, 2025, was introduced to Parliament to reform and consolidate the law relating to the regulation of drugs, medical devices, cosmetics, and other health products in Uganda. The Bill seeks to repeal and replace the National Drug Policy and Authority Act, Cap. 198, which has been in force since 1993. Over the years, the pharmaceutical and health products landscape has evolved significantly, with new technologies, emerging diseases, and complex challenges such as counterfeit medicines and antimicrobial resistance.

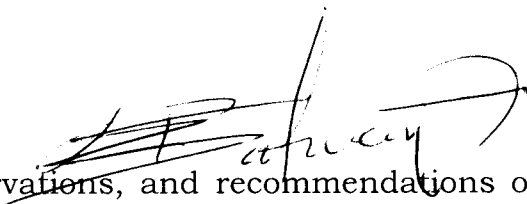
The existing legal framework has therefore become inadequate to effectively regulate the sector and ensure the safety, efficacy, and quality of health products available on the market. The proposed law introduces progressive provisions to enhance pharmacovigilance, promote rational use of medicines, strengthen control over clinical trials, and improve post-market surveillance. It further provides for collaboration with regional and international regulatory agencies, in line with global best practices.

Upon referral of the Bill to the Committee for a detailed examination and scrutiny in accordance with Rule 135 (2), the Committee undertook consultations with key stakeholders, including the Ministry of Health, National Drug Authority, Uganda Medical and Dental Practitioners Council, pharmaceutical industry representatives and health professionals, among others (*a detailed list is enumerated under methodology*). The Committee also reviewed relevant regional and international legal instruments to ensure the proposed framework aligns with contemporary regulatory standards.



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This report presents the findings, observations, and recommendations of the Committee on the National Drug and Health Products Authority Bill, 2025.

3.0 Object of the Bill

The National Drug and Health Products Authority Bill, 2025 seeks to repeal the National Drug Policy and Authority, Cap. 198 and establish the *National Drug and Health Products Authority (NDHPA)* as the central body responsible for the regulation, control, and supervision of the manufacture, importation, exportation, distribution, and use of drugs and health products in Uganda. It also seeks to expand the regulatory mandate of the Authority to cover a wider range of health products, including medical devices, cosmetic products, public health products, nutritional supplements, diagnostics, biologicals and vaccines.

The Bill also seeks to provide a framework for pharmacovigilance and strengthening of enforcement by granting inspectors powers to seal premises, test products, recall and withdrawal substandard products, and prosecute offenders.

The Bill therefore aims to -

- (a) establish the National Drug and Health Products Authority (NDHPA), replacing the existing National Drug Authority (NDA);
- (b) provide for the functions and powers of the Authority;
- (c) regulate the manufacture, distribution, importation, exportation, and supply of drugs, medical devices, cosmetics products, public health products and nutritional supplements;
- (d) provide for the administration and enforcement of the Act;
- (e) repeal the National Drug Policy and Authority Act, Cap. 198;
- (f) amend the Food and Drug Act, Cap. 307; and
- (g) amend the Narcotic Drugs and Psychotropic Substances (Control) Act, Cap, 37.

4.0 Legal framework

4.1 Existing Laws affected by the Bill

The laws affected by the Bill include:

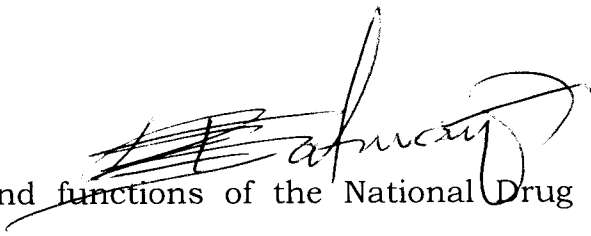
- i. National Drug Policy and Authority Act, Cap. 198 (s. 120 (1))
- ii. Food and Drugs Act, Cap. 307 (s.120 (2))
- iii. Pharmacy and Drugs Act, Cap.309
- iv. Narcotic Drugs and Psychotropic Substances (Control) Act, Cap. 37 (s. 120 (3))
- v. Uganda National Bureau of Standards Act, Cap. 210
- vi. Medical and Dental Practitioners Act, Cap. 300
- vii. Nurses and Midwives Act, Cap 296
- viii. Allied Health Professionals Act, Cap. 296
- ix. Public Health Act. Cap 310
- x. National Medical Stores Act, Cap. 201 (s. 109)
- xi. Traditional and Complementary Medicine Act, Cap. 304
- xii. Uganda Communications Act, Cap. 103
- xiii. Veterinary Surgeons Act, Cap. 306
- xiv. Mental Health Act, Cap. 308
- xv. Companies Act, Cap. 106
- xvi. Sale of Goods and Supply Act, Cap. 292

4.2 Defects in the National Drug Policy and Authority Act (Current law)

Parliament established the National Drug Authority (NDA) in 1993 through the National Drug Policy and Authority Act. The NDA’s mandate was primarily to regulate the availability, quality, and safety of of both human and veterinary medicines. At that time, the pharmaceutical industry in Uganda was small, with most drugs imported, and the immediate challenge was to combat the manufacture and distribution of fake and expired medicines. The law has not been substantively amended since enactment and yet, Uganda’s health sector has evolved dramatically.

Over three decades later, Uganda’s health sector has transformed significantly, while the National Drug Policy and Authority Act which was enacted in 1993 has not been directly amended since then. And hence does not address;

- (a) new health products such as medical devices, cosmetic products, nutritional supplements, and other health-related products;
- (b) complex drug markets, with falsified and substandard products posing risks of treatment failure and antimicrobial resistance; and
- (c) global best practices under the World Health Organization (WHO) which require broader and more integrated regulation,



hence the need to align the mandate and functions of the National Drug Authority to the current challenges.

In addition, the narrow scope of the mandate of the Authority poses a challenge in the execution of its mandate as a regulator. Furthermore, the existing law does not regulate important aspects of the sector such as pharmacies in health units, the distribution of drugs, the release of vaccines and biologicals by lot, the recall and withdrawal of drugs that are unsuitable for use among other matters and yet these weaknesses constrain effective enforcement and public health protection.

4.3 Alignment of the Bill with National Policy Frameworks

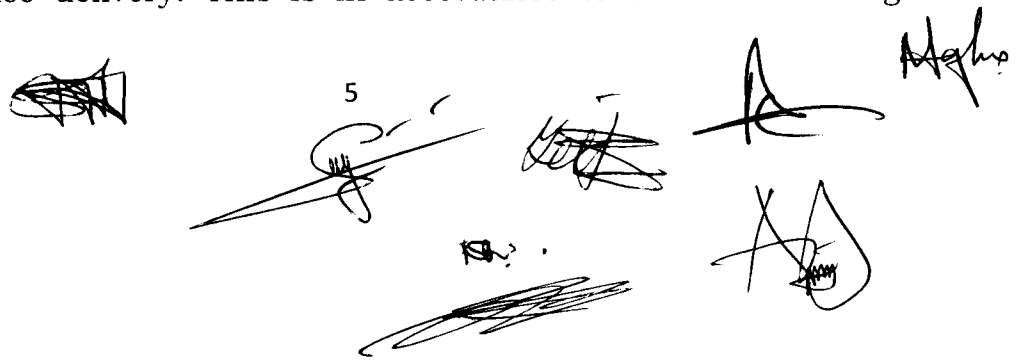
The Bill responds directly to Uganda’s broader policy commitments, including

- (a) Uganda Vision 2040: Envisions a healthy and productive population as a driver of socioeconomic transformation;
- (b) National Development Plan (NDP IV) FY2025/26 – 2029/30 prioritises strengthening health systems, including pharmaceuticals and medical technologies;
- (c) Health Sector Development Plan (HSDP II) 2020/21–2024/25m calls for improved regulation of medicines, health technologies, and innovations; and
- (d) Industrialisation Agenda encourages local pharmaceutical manufacturing, which requires a strong and credible regulator to meet domestic and export standards.

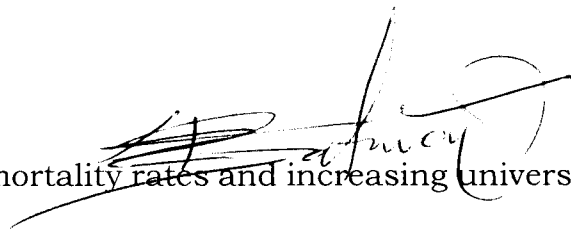
By repealing the old law and enacting the proposed Bill into law, Uganda strengthens the institutional framework for health governance, aligns with EAC harmonisation efforts, and positions itself for integration into international health spaces.

4.3 Compliance of the Bill to NDP IV Priorities

The bill is aligned to the strategic objectives especially the NDP IV Strategic Objective 2 and 4 where by it enhances quality assurance, safety, and availability of medicines and health products, directly supporting NDP IV’s goal to improve healthcare access and outcome, regulates the circulation of substandard and counterfeit medicines, lowering disease burden and improving productivity and strengthened pharmacovigilance and health product traceability align with NDP IV’s emphasis on modernizing health infrastructure and digital transformation for efficient service delivery. This is in accordance to the NDP IV target of



reducing maternal, infant, and neonatal mortality rates and increasing universal health coverage.



4.4 Alignment of the Bill to sustainable Development Goals SDG 3 and 5: Good Health and well-being; and gender

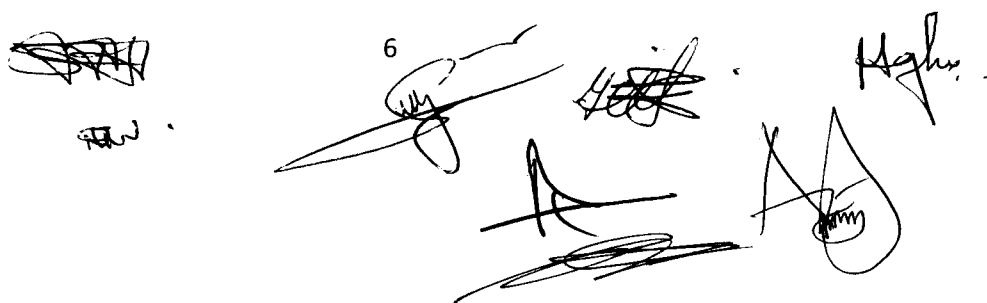
The Bill emphasises the stricter quality-control, pharmacovigilance, and batch-testing to reduce substandard or falsified medicines, improving treatment outcomes by-

- (a) empowering government to encourage research by persons carrying out research and development in herbal and other medical products.
- (b) recognizing different core cadres of health professionals including medical practitioners, dental practitioners, Nurses, allied health professionals to carry out different functions as provided in the Bill for boosting the health sector,
- (c) mandating the Minister to ensure gender balance in appointing members of the Board and empowering health professionals at the different levels of health care on safe drug handling and adverse-event reporting.

5.0 Expected Outcomes and Results of enacting the Bill

The enactment of the National Drug and Health Products Authority Bill, 2025, is expected to yield transformative outcomes for Uganda's health sector by strengthening the regulation, quality, safety, efficacy, and accessibility of all health products. The key intended results include;

- (a) establishment of a unified, autonomous, and modern regulatory authority; the National Drug and Health Products Authority (NDHPA) with expanded mandate to regulate not only medicines but also medical devices, diagnostics, blood and blood products, cosmetics, nutritional supplements, public health products, herbal and complementary medicines, and other emerging health technologies.
- (b) Fast-tracking Uganda's attainment of World Health Organization Maturity Level 3 (WHO ML3), signaling a stable, well- functioning, and internationally recognized regulatory system. Achieving ML3 will allow Uganda to benefit from increased participation in global procurement mechanisms like the Global Fund, GAVI, and UNICEF, which prioritize sourcing from countries with WHO-compliant regulatory authorities. Significantly, achieving ML3 will enhance Uganda's extent of participation in the operational structure of the



African Medicines Agency (AMA) and bolster local pharmaceutical manufacturing and attract external investment.

- (c) It will also improve public health outcomes through reduced circulation of substandard and falsified products, enhanced pharmacovigilance, rational use of medicines, and better treatment outcomes. The World Health Organization (WHO) requires national regulatory authorities to align with global best practices for regulation of medical products and to meet certain benchmarks for quality assurance.
- (d) Fostering increased public trust in the health system, attract investments in local pharmaceutical manufacturing, enable Uganda to participate in global health supply chains and donor-supported programs, and position the country as a regional regulatory leader under frameworks such as the African Medicines Agency (AMA), the Intergovernmental Authority on Development (IGAD) and East African Community Medicines Regulatory Harmonization Program (EAC-MRH).
- (e) Enhancing enforcement powers of authorized persons by empowering inspectors to recall unsafe products, seal premises, and destroy harmful goods.
- (f) Establishing a National Drug and Health Products Laboratory as centre of excellence for testing and certification.

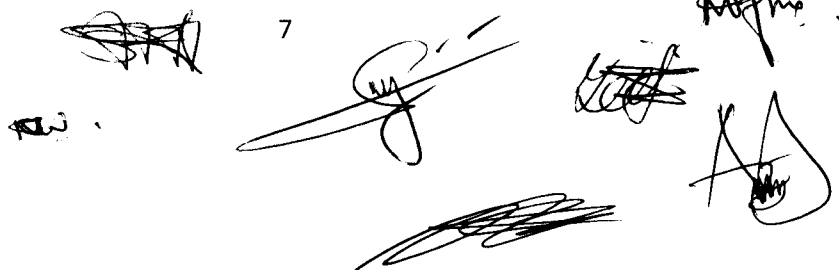
6.0 METHODOLOGY

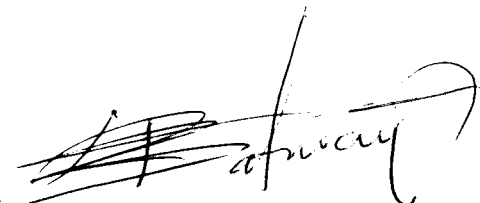
The Committee was guided by the provisions of Rule 135 of the Rules of Procedure of Parliament to examine the Bill in detail and make all such inquiries in relation to it. As such, the Committee employed the following methods of work;

Meetings

During the consideration of the Bill, the Committee called for public participation in the legislative process by running adverts in the Daily Monitor and New Vision Newspapers, upon which the Committee held consultative meetings with the following stakeholders;

1. Ministry of Health (**MoH**)
2. Ministry of Agriculture, Animal Industry and Fisheries (**MAAIF**)
3. Ministry of Trade, Industry and Cooperatives (**MTIC**)
4. National Drug Authority (**NDA**)
5. National Medical Stores (**NMS**)
6. Pharmaceutical Society of Uganda (**PSU**)
7. Joint Medical Stores (**JMS**)
8. Uganda Law Society (**ULS**)



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9. Uganda National Bureau of Standards (**UNBS**)
 10. The Medical and Dental Practitioners Council
 11. The Directorate of Government Analytical Laboratory, Ministry Of Internal Affairs
 12. Uganda Investment Authority (**UIA**)
 13. Association of Pharmaceutical Scientists of Uganda
 14. Uganda Pharmaceutical Manufacturers Association
 15. Uganda Medical Association
 16. Uganda National Health Consumers Organization (**UNHCO**)
 17. National Union of Pharmaceutical and Pharmacy Workers, Uganda (**NUPAPWU**)
 18. National Council for Traditional Healers and Herbalists Associations (**NACOTHA**)
 19. The Graduate Medical Clinical Officer's Association of Uganda (**GMCOA**)
 20. The Uganda Society of Professional Chemists (**USPC**)
 21. The Uganda Pharmacy Owners Association (**UOPA**)
 22. Natural Chemo Therapeutics Research Organization (**NCRI**)
 23. Uganda National Health Research Organization (**UNHRO**)
 24. Nutrition Society of Uganda (supplements)
 25. Civil Society Alliance for Nutrition Uganda (**CISANU**)
 26. Federation of Private Medical Practitioners (under dental practitioner's council)
 27. Parliamentary Forum on Antimicrobial Resistance
 28. Association of Ear, Nose, Throat Clinical Officers (U) Ltd
 29. The Optometrists Association of Uganda
 30. Uganda National Association of Medical and Hospital Engineering (**UNAMHE**)
 31. The Uganda Society of Professional Chemists

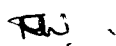
Written Submissions

The Committee received written submissions from the following stakeholders;

1. Mbarara University of Science and Technology (Faculty of Medicine-Department of Pharmaceutical Sciences)
2. Uganda National Health Research Organisation (**UNHRO**)
3. Association of Biomedical Engineers and Technicians of Uganda (ABETU)
4. Kennedy Odokonyero an independent consultant and Local Qualified Person
5. Pharmacovigilance (QPv) in Uganda
6. Women in Pharmacy
7. Society of Radiography of Uganda



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8. Uganda Manufacturers Authority (UMA)
 9. Pharmaceutical Technologists/Scientists of Uganda of Uganda
 10. The Atomic Energy Council
 11. Call to Action for Rare Diseases Research and Advocacy
 12. Kampala City Traders Association (KACITA (Importers and Exporters of Cosmetics)
 13. Uganda Veterinary Association
 14. School of Biomedical Sciences
 15. School of Pharmacy Makerere University
 16. The Allied Health Professionals Council
 17. College of Veterinary Medicine, Animal Resources and Bio-Security

Harmonisation meetings

Harmonisation meetings on the Bill took place between the Committee of Health of Parliament, the Minister responsible for Health and the office of the Attorney General.

7.0 COMMITTEE ANALYSIS, OBSERVATIONS AND RECOMMENDATIONS.

7.1 Certificate of Financial Implications

The Committee notes that section 74(1) of the Public Finance Management Act, Cap. 171, and rule 124(1) of the Rules of Procedure of Parliament require every Bill to be accompanied by a Certificate of Financial Implications issued by the Minister responsible for finance. The Committee considered the Certificate of Financial Implications accompanying the Bill and observed as follows—

- (a) the Certificate sets out the broad objectives of the Bill and states that its implementation will be financed through fees collected by the Authority, grants, loans and other lawful sources;
- (b) the Certificate indicates that the Bill is intended to strengthen the national regulatory system for health products, enhance quality assurance and pharmacovigilance through the establishment of a statutory laboratory and a safety monitoring framework, and improve coordination among key regulatory institutions;
- (c) the Certificate further shows that the Bill aligns with the Fourth National Development Plan (NDPIV) by contributing to increased life expectancy, reduction of the disease burden, increased local production of essential



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medicines and health commodities from 30% to 60% by 2030, and improved governance and accountability in public institutions; and

- (d) the Certificate indicates that the Bill is projected to yield an Economic Net Present Value of Shs. 984.3 billion and an Economic Internal Rate of Return of 21.9%, which demonstrates strong expected returns to the economy.

7.2 General observation on the principles of the Bill

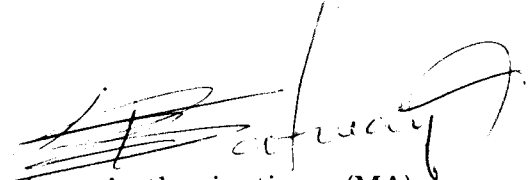
The Committee examined the National Drug and Health Products Authority Bill and noted that its primary objective is to repeal and replace the National Drug Authority Act, Cap. 206, in order to establish the National Drug and Health Products Authority with an expanded mandate. The Bill seeks to move beyond the regulation of drugs and provide for the regulation of a wider range of human health-related products, including medical devices, cosmetic products and nutritional supplements. The Bill also empowers the Authority to collaborate with governmental, regional and international agencies in order to modernise regulatory oversight and align Uganda's regulatory framework with international best practices.

The Committee appreciates the policy intention behind the Bill. The Committee notes that the repeal of the 1993 law and the introduction of a broader legal framework will reduce legal ambiguity, strengthen consumer protection and enhance the regulation of emerging categories of health products. The Committee further notes that a modern and coherent regulatory framework is essential for public health protection, promotion of local manufacturing, investor confidence and a predictable business environment.

The Committee notes that, the Bill will improve quality assurance, strengthen pharmacovigilance, enhance post-market surveillance and promote more efficient regulatory coordination across the health sector. The Bill is therefore timely and relevant in light of developments in health technologies, international trade, public health risks and Uganda's broader strategy to improve regulatory systems.

Furthermore, this bill paves way for Uganda to meet the requirements of the World Health Organisation Global Benchmarking Requirements and Good Regulatory Practices and will lead to the realisation of *WHO Maturity Level 3 or 4* through addressing the foundational legal requirements for the regulation of drugs including vaccines and medical devices by providing for the required

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regulatory functions of; Registration and Marketing Authorization (MA), Pharmacovigilance (VL), Market Surveillance and Control (MC), Licensing Establishments (LI), Regulatory Inspection (RI), Laboratory Testing (LT), Clinical Trial Oversight (CT), National Regulatory Authority Lot Release (LR), and the National Regulatory Systems.

The Bill also aligns with Africa's aspiration to have a uniformed regulatory regime through the African Union (AU) Model Law for the Regulation of Medical Products which countries across the continent are domesticating.

The Committee notes that the passing of this law will accelerate Uganda's ability to protect and preserve the health of her citizens thereby enhancing productivity, increase Uganda's competitiveness on the international pharmaceutical and biopharmaceutical market as well enhance the global reputation of the country's pharmaceutical and biopharmaceutical sectors.

7.2.1 Implications of the Bill on Investment

Observation

The Committee observed that certain provisions of the Bill may increase the cost of doing business due to multiple licences that are to be issued by different regulatory authorities, high fees arising from different applications and absence of statutory timelines for regulatory decisions. The Committee noted that investors in pharmaceuticals and medical devices operate within strict commercial timelines and that prolonged processes may affect market entry and increase the risk of product expiry.

Recommendation

The Committee recommends that the Bill should support investment by—

- (a) providing clear statutory timelines for licensing and approval of decisions.
- (b) establishing a comprehensive framework that will evaluate and strengthen the regulatory systems of medicines, vaccines, and medical devices through empowerment of the Authority to licence manufacturers, suppliers, distributors, importers or exporters in line with the Global Benchmarking Tool (GBT).
- (c) ensuring that the provisions on dual regulation in the Bill is amended as per Cabinet principles which clearly stipulate which products should be regulated under the Bill.

Notwithstanding the above, the Committee observed that a number of provisions in the Bill require amendment in order to make the law practical, fair, technically sound and responsive to Uganda’s institutional and socio-economic realities.

7.2.3 Overlapping and Duplication of Regulatory Mandates

Observation

The Committee observed that some provisions of the Bill overlap with the mandates of existing regulatory bodies, including the Ministry of Agriculture, Animal Industry and Fisheries, Trade Industry and Cooperatives, Uganda National Bureau of Standards and the National Council for Science and Technology. The Committee noted that duplication may lead to double compliance costs, delays in approvals, inconsistent decisions and uncertainty for businesses.

The Committee noted with concern, that the Bill was empowering two regulatory bodies, the Uganda National Bureau of Standards and the National Drug Authority to set standards for regulated products under the Act. The committee was guided by the Principles approved by Cabinet under Minute 170 (CT 2023) which noted that;

- (a) the Uganda National Bureau of standards would cede the mandate or regulation of medical devices to the National Drug Authority;
- (b) the National Drug Authority would regulate medicines, cosmetic products, house hold chemicals, public health products and nutritional supplements;
- (c) the Uganda National Bureau of Standards would regulate all other products except those regulated by the National Drug Authority and any other specialized agency as established by law; and
- (d) the Uganda National Bureau of Standards would remain a custodian of standards in accordance with the law.

Recommendation

The Committee recommends that—

- (a) the mandate of setting standards for drugs and regulated products under the Act should be left to the Authority in order to avoid confusing the traders with double regulation in relation to standards;
- (b) the Authority should coordinate with UNBS and other relevant agencies to ensure harmonised approval processes; and
- (c) the Bill should avoid duplication of inspection, certification and enforcement mandates.

7.2.4 Disparity in the fees charged under different clauses

Observation

The Committee observes that similar or related offences under different clauses impose different penalties and fails to distinguish between offences of varying gravity which creates disparities. The penalty clauses do not make a clear distinction between serious violations that endanger public health such as falsified medicines, deception of consumers or advertisement and minor administrative lapses (such as delayed registration). This contravenes the principle of proportionality of punishment under Article 28 of the Constitution, and may discourage compliance or over-penalise small-scale operators.

Recommendation:

The penalties should be scaled to reflect the nature and gravity of the offence.

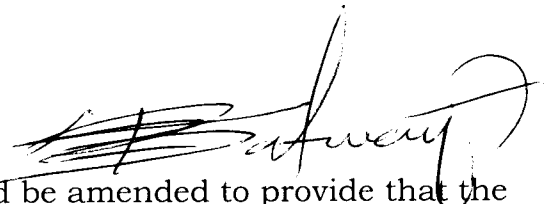
7.3 Clause-by-Clause Observations and Recommendations

Clause 6. Directions of the Minister

Observation

Clause 6(1) and (2) empowers the Minister to give policy directions to the Authority in writing, and that the Authority must comply with the Minister's directions. The Committee observed that this provision gives extensive authority to the Minister which may undermine the independence of the Authority in matters requiring scientific and technical judgment. The Committee noted that the regulation of drugs and health products involves highly specialised matters which require evidence-based and technical decision-making.

Recommendation



The committee recommends that the Bill should be amended to provide that the directions of the Minister should not adversely affect or interfere with the independence of the Authority, or the performance of the functions and exercise of the powers of the Authority under this Act so as to preserve regulatory independence, promote science-based decision-making and maintain public confidence.

Clause 7: Board of Directors

Observation

The Committee notes that clause 7(1) seeks to establish a Board of Directors appointed by the Minister, as the governing body of the Authority. However, it does not sufficiently provide for the qualifications and experience required of members of the Board. The Committee is concerned that this omission may permit the appointment of persons who lack the technical competence necessary to provide effective oversight over the regulation of drugs and health products. Given that the Bill expands the mandate of the Authority beyond pharmaceuticals to include medical devices, cosmetic products, nutritional supplements and other health products, the Committee observed that these areas present distinct technical, safety and regulatory considerations which require specialised oversight.

The Committee is of the view that the Board ought to collectively possess the expertise necessary to support informed decision-making, effective governance and proper supervision of the Authority’s regulatory functions. The Committee further notes that provision should be made for representation of women on the Board in line with the constitutional policy on affirmative action.

Recommendation

- The Committee recommends that the clause establishing the Board be amended to expressly provide for the composition, qualifications of members of the Board, and to require gender representation, in order to promote professionalism, transparency, accountability, equality and effective governance of the Authority.









- The Committee further recommends that the Bill should ensure that the Board is composed of persons with the expertise necessary to oversee a specialised regulatory body.

Clause 8. Tenure of office of members of the Board and clause 11 on the Executive Director.

Observation

The Committee notes that stakeholders expressed concern about the passing of the Bill without clear provision for the tenure of office of members of the Board, the tenure of office of the Executive Director, and the manner in which vacancies on the Board are to be filled. Stakeholders informed the Committee that there is need to prescribe a definite term of office of four years for a member of the Board and five years for the Executive Director, with eligibility for re-appointment for one further term. The Committee observed that such provision would promote certainty, accountability and continuity in the governance and management of the Authority, while allowing renewal on the basis of merit and performance.

The Committee further considered it necessary to provide for the manner in which vacancies on the Board are to be filled, in order to ensure the effective functioning of the Board.

Recommendation

The Committee recommends that the Bill be amended to;

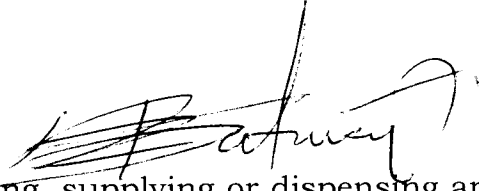
- (a) prescribe a clear and definite tenure of office for members of the Board and the Executive Director, with eligibility for re-appointment for one more term, in order to promote certainty, accountability and continuity in the governance of the Authority; and
- (b) require the Minister to fill vacancies on the Board in accordance with the procedure prescribed by regulations made under the Act, so as to ensure timely replacement of members and the efficient functioning of the Board.

Clauses 21, 56, 64, 71 and 77 on Registration, notification and listing of drugs and regulated products

Observation:

Clauses 21(1), 56(1), 64(1), 71(1) and 77(1) prohibit any person from

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manufacturing, importing, exporting, distributing, supplying or dispensing any drug or regulated product unless the drug or regulated product is registered or notified by the Authority. However, Subclause 21(3), 56(2), 64(2), 71(2) and 77(2) exempt application of the section including under situations of carrying out a clinical trial, personal use, emergency situation or for purposes of registration, however it leaves the determination of the application of the exemption to the person applying and not at the discretion of the Authority.

Recommendation

- The said subclauses should be amended to empower the Authority to determine the circumstances under which a person could qualify for disapplication of the requirement for registration, notification or listing.
- Basing on submission of stake holders, the exemptions should be expanded to include for compassionate use, under extraordinary circumstances and for approved scientific education and research, subject to the regulations to be made by the Authority.

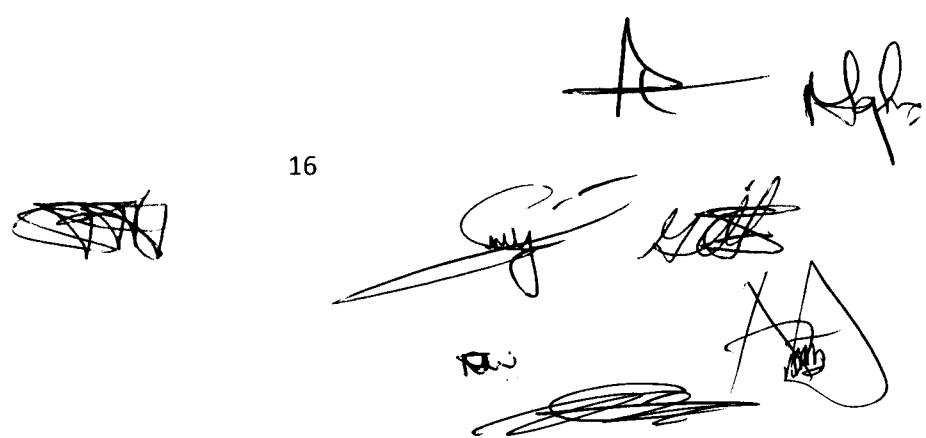
Clauses 25, 58, 66, 73 and 79 on licensing of importation of drugs and regulated products

Observation:

Clauses 25(1), 58(1), 66(1), 73(1) and 79(1) prohibit any person from importing any drug or regulated product unless the drug or product is licensed by the Authority. However, Sub clause 25(2), 58(2), 66(2), 73(2) and 79(2) exempt application of the section including under situations of carrying out a clinical trial, personal use, emergency situation or for purposes of registration, however when the committee interacted with stakeholders, it was brought to the knowledge of the Committee that there are other exceptional circumstances that could be considered.

Recommendation

- The exemptions should be expanded to include for compassionate use, under extraordinary circumstances and for approved scientific education and research, subject to the regulations to be made by the Authority.



Clause 28: Requirement for a Pharmacist as a Director of a Pharmacy or as a partner

The Committee considered clause 28(4)(a), which requires that where an applicant for licencing to operate a pharmacy is a body corporate, at least one of the directors shall be a registered pharmacist, and clause 28(4)(c), which requires that where the applicant is a partnership, one of the partners shall be a pharmacist regulated under the Pharmacy and Drug Act. The Committee noted that the proposal attracted divergent views from stakeholders. Those in support argued that pharmacy is a highly regulated public health activity affecting patient safety and that the inclusion of a pharmacist in the governance structure promotes professional oversight, compliance with the law, accountability, and protection against purely commercial decision-making. They further observed that the requirement is not novel, as section 17(1)(c) and (d) of the National Drug Policy and Authority Act already provides for a pharmacist director or partner in similar circumstances.

The Committee also considered concerns raised by stakeholders who opposed the provision. These included the view that requiring a pharmacist to be a director or partner may restrict business flexibility, interfere with ordinary corporate governance principles under the Companies Act, duplicate the professional accountability already provided for through the requirement for a pharmacist responsible for immediate supervision, and potentially discourage investment in the pharmaceutical sector.

The Committee noted that comparative jurisdictions take different approaches on whether a pharmacist should be a director of a corporate body carrying on the business of pharmacy. In **Kenya, section 21(1)(b) of the Pharmacy and Poisons Act, Cap. 244** expressly requires that where a body corporate carries on the business of a pharmacist, the business shall be under the management of a superintendent who is a registered pharmacist and a member of the board of directors of the body corporate, and who is not acting in a similar capacity for another body corporate. In Nigeria, **the Pharmacy Council of Nigeria (Establishment) Act, 2022** requires every pharmaceutical premises to be under the direct supervision and control of a Superintendent Pharmacist and refers to the “profile of Pharmacist Director,” though without making the director requirement fully explicit in the Act itself; however, the **2025 PCN Guidelines for Registration of Pharmacists and Pharmaceutical Premises** expressly provide that there must be at least one pharmacist on the board of directors.

The Committee further noted that other jurisdictions do not expressly require a pharmacist to be a director of a corporate pharmacy business. In **Tanzania**, the current **Pharmacy Act framework and the Pharmacy (Premises Registration) Regulations, 2020** require a superintendent pharmacist and recognise the responsibilities of the owner and superintendent, but do not expressly require the pharmacist to be a director, although the older Pharmaceutical and Poisons Act, 1978 had such a requirement. Similarly, in the **United Kingdom, section 71(1)(a) of the Medicines Act 1968** requires a body corporate carrying on retail pharmacy business to have a superintendent pharmacist, while the Pharmacy (Responsible Pharmacists, Superintendent Pharmacists etc.) Order 2022 reinforces the role of the superintendent as the professional lead, without requiring that person to be a company director.

The Committee also noted that the WHO/FIP Good Pharmacy Practice standards do not require a pharmacist to be a director, but instead require pharmacy services to be organised in a manner that ensures patient welfare, quality and safe use of medicines, and effective professional control, leaving the question of governance structure to national law.

Observation

Upon consideration of the different views of stakeholders, the Committee observed that the business of pharmacy directly concerns public health and patient safety and therefore requires meaningful professional oversight. The Committee further noted that the requirement for a pharmacist director or partner has long existed in Uganda’s law and is therefore not a new policy departure.

Recommendation

The Committee accordingly recommends that clauses 28(4)(a) and (c) be maintained as proposed in the Bill, in order to safeguard the public in relation to the consumption of drugs and to ensure that a pharmacist serving as a director or partner bears responsibility, to the extent of his or her professional role, for compliance of the business with the law governing pharmaceutical practice.

Clause 29 – Operation of Drug shops

Observation:

The Committee noted that drug shops play an important role in improving access

to essential medicines, especially in rural and under served areas where pharmacies and health facilities may not be readily available. The Committee, however, observed that because drug shops handle medicines whose improper sale, storage or dispensing may pose risks to public health, their operation must be subject to strict regulation.

The Committee further noted that the Bill provides a clearer regulatory framework for drug shops through licensing, compliance with prescribed conditions, and supervision by the Authority.

Recommendation

- The Committee finds it necessary to ensure that drug shops operate only within the limits permitted by law, maintain proper standards for premises and storage, and do not engage in the sale or dispensing of medicines for which they are not authorised.
- The Committee also emphasizes the need to distinguish drug shops from pharmacies so as to preserve professional standards and accountability in the medicines supply chain.

Clause 35. Classification of drugs

The Committee considered clause 35 on the classification of drugs and observed that the clause is intended to provide a clearer framework for the control, prescription and dispensing of drugs according to their level of risk. The Committee noted that the proposed amendment usefully distinguishes between **Class AI drugs**, comprising narcotic drugs and psychotropic substances; **Class AII drugs**, comprising other prescription-only drugs; **Class B drugs**, which may be dispensed without prescription as well as **class C** which are over the counter drugs and **class E drugs** which are general sales drugs. The Committee observed that this classification is necessary in order to promote rational use of medicines and to ensure that drugs with a higher potential for abuse, dependency or harm are subjected to stricter professional control. The clause also classifies class A and class B drugs as restricted drugs.

The Committee observed that the provision in the Bill does not clearly distinguish between the act of prescribing and the act of dispensing by which Class AI and Class AII drugs are distinguished from other classes of drugs. The Committee noted that this distinction is necessary to promote patient safety, rational use of medicines and clarity of professional responsibility.

The Committee also observed that the Bill does not provide a penalty for dispensing contrary to the clause and yet it is necessary to strengthen enforcement and deter unlawful dispensing of drugs.

Recommendation

- The Committee recommends that it is necessary to amend the provision to clearly distinguish between prescription and dispensing, so that prescription-only drugs are supplied only on the authority of an authorised prescriber, while dispensing remains the responsibility of a pharmacist.
- The Committee further recommends the insertion of a penalty provision in order to backstop compliance, enhance deterrence and support effective enforcement of the classification regime under the Bill.

Clause 38: Supply, dispensing and mixing of restricted drugs by nurses, midwives and dispensers

Observation

The Committee welcomed the inclusion of cadres enrolled under the Allied Health Professionals Act and the Nurses and Midwives Act in the prescribing, supply and dispensing of restricted drugs. The Committee observed that this will strengthen health service delivery, particularly in areas where these cadres serve as the primary frontline providers. The Committee further noted that these cadres have historically played an important role in Uganda’s health system.

The Committee also received submissions in respect of optometrists and ENT clinical officers, who prescribe medicines and medical devices within their respective scopes of practice and provide specialised services across the country.

Recommendation

- The Committee recommends that the provision in the Bill is a positive step, as it preserves the prescribing rights of cadres already authorised under the Allied Health Professionals Council Act, within their respective scopes of practice.
- The Committee further recommends that, in making regulations under this clause, the Minister should—

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- (a) recognise optometrists as prescribers of ocular therapeutic pharmaceutical agents within their scope of practice;
- (b) provide for the integration of optometrists into the national pharmacovigilance system; and
- (c) recognise ENT clinical officers as prescribers of medicines and relevant medical devices necessary for specialised ear, nose and throat care, within their scope of practice.
- (d) recognise the other categories of prescribers and dispensers who may not be recognised under the Allied Health Professionals Act and the Nurses and Midwives Act.

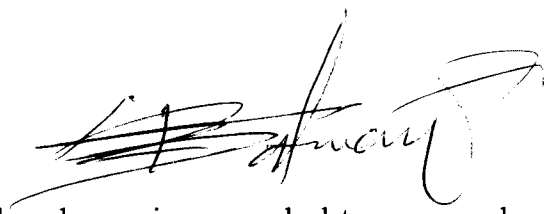
Clause 50 and clause 90. Authorisation to Conduct Clinical Trials or field trials for drugs and regulated products

Observation

The Committee appreciates the inclusion of provisions on clinical trials for drugs and regulated products and field trials for medical devices, as they are necessary to ensure ethical compliance, informed consent and patient safety. The Committee was informed by the Ministry of Health that it was important that the Bill considers clinical trials or field trials conducted by the Ministry in the public interest to be done expeditiously to enable the Ministry to seamlessly and expeditiously execute its mandate in matters of public health importance, including emergencies, disease outbreaks, surveillance interventions and other interventions undertaken in the national interest, while at the same time requiring the Ministry to conduct such trials in accordance with good clinical practices prescribed by regulations made under the Act.

The Committee, however, observes that even where a trial is undertaken in the public interest, the safety, dignity and rights of human participants must remain paramount. The exemption should therefore not be construed as excluding public interest trials from oversight, ethical standards, safety monitoring or accountability requirements. Clinical trials for drugs and other regulated products inherently carry potential risks to participants and the public, and must be conducted within a framework that guarantees scientific validity, informed consent where applicable, protection from harm, adverse event reporting, and post-trial accountability.

Recommendation



The Committee recommends that the clause is amended to expressly provide for clinical trials or field trials conducted by the Ministry in the public interest are conducted expeditiously but remain subject to applicable ethical approval, and compliance with good clinical practice prescribed under the Act.

Clause 52 - Establishment of Pharmacovigilance systems

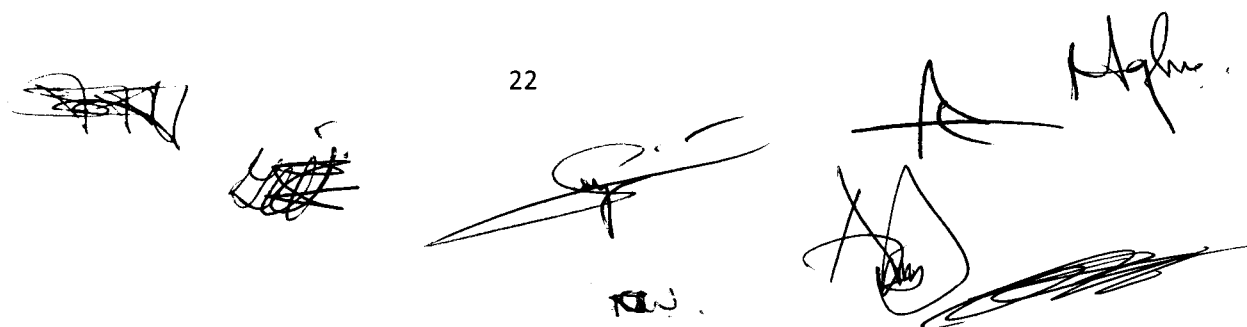
The Committee notes that pharmacovigilance is an essential component of regulation of drugs and other regulated products because it enables the continuous monitoring of the safety, quality and performance of products after they have been authorised for use or placed on the market. The Committee observes that whereas pre-market assessment and clinical trials are important in establishing the safety, efficacy and quality of a product, they may not detect all adverse events, adverse reactions, long-term effects, product defects, misuse, medication errors or risks that arise when the product is used by a wider and more diverse population under actual conditions of use.

The Committee further notes that an effective pharmacovigilance system is necessary for the early detection, assessment, understanding and prevention of adverse events, adverse reactions and other product-related problems. It is critical in protecting patients and the public from avoidable harm, informing timely regulatory action such as safety alerts, label changes, restrictions, recalls or suspension of products, and strengthening public confidence in the health system. Pharmacovigilance is particularly important for drugs, vaccines, biologicals, medical devices and other regulated products whose safety profiles may evolve over time.

The Committee also observes that pharmacovigilance supports rational use of medicines and regulated products, promotes accountability among manufacturers, importers, distributors and health professionals, and enables the Authority to make evidence-based regulatory decisions. In the absence of a robust pharmacovigilance framework, unsafe or poor-quality products may remain in circulation undetected, thereby exposing the public to serious health risks.

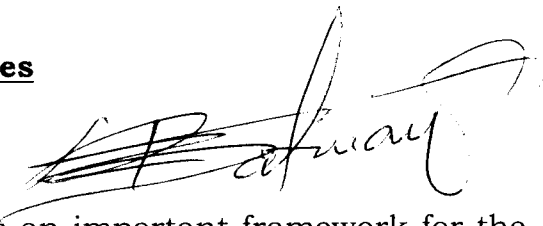
Recommendation:

The Committee recommends that the clause should be amended to subject the approval of the pharmacovigilance system to good manufacturing practices.



Clauses 55-62. Regulation of Medical Devices

Observation



The Committee notes that the Bill establishes an important framework for the regulation of medical devices, including their registration, notification, listing, importation, exportation, distribution, licensing of premises, and reporting of defects and adverse reactions. This is necessary to ensure that medical devices placed on the market are safe, of good quality and fit for their intended use.

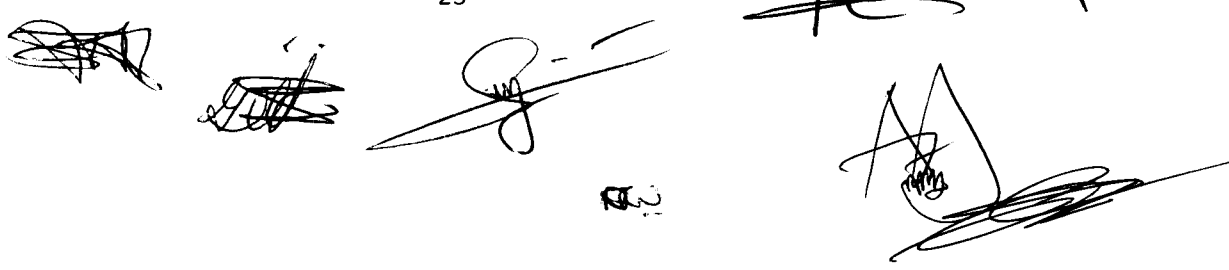
The Committee further notes that concerns were raised about possible double regulation between the Authority and the Uganda National Bureau of Standards. However, this concern was resolved through the Cabinet Principles 170 (CT 023) which empowered the Authority to regulate medical devices in the country in order to avoid fragmented oversight. The Committee therefore observes that the Authority should remain the lead regulator, with coordination between the two institutions where standards are applicable.

The Committee also received concerns regarding the numerous fees applicable to medical devices and related products, including fees for registration, notification or listing, manufacturing, importation or distribution among others and noted that the various fees if not harmonized will increase healthcare costs, restrict access to essential medical devices and discourage local research, innovation and manufacturing. The Committee was also alerted of the various professionals related to operation or usage of medical devices such as the bio-medical engineers and bio-medical technicians among others and yet these were not mentioned anywhere in the Bill.

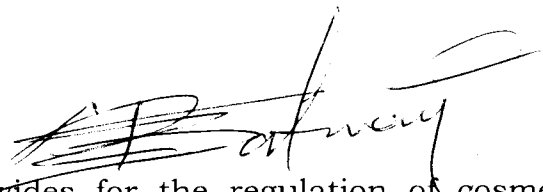
Recommendation

- The Committee recommends that the Minister, while making regulations in relation to the fee structure applicable to medical devices, should consider making the structure affordable, proportionate and supportive of access, innovation and local production.
- The Committee further recommends that part VI of the Bill should be amended to refer to technical expertise for medical devices including bio-medical engineers and bio-medical technicians.

Clauses 63-69. Regulation of Cosmetic products



Observation



The Committee notes that the Bill provides for the regulation of cosmetic products, including registration, notification, listing, importation, export licensing, distribution licensing, licensing of premises, and the reporting of defects and adverse reactions. The Committee appreciates the inclusion of cosmetic products within the scope of the Bill because such products may pose risks to public health where they contain harmful substances, are contaminated, are substandard, or are placed on the market without adequate regulatory oversight.

The Committee, however, observed concerns from stakeholders regarding the possibility of double regulation between the Authority and the Uganda National Bureau of Standards, particularly in relation to standards, quality control and market oversight of cosmetic products. The Committee notes that this matter was resolved through a Cabinet Memorandum which authorised the Authority to regulate cosmetic products that contain steroids, parabens, phthalates, hydroquinone, retinoids or sunscreens, the rest of the cosmetic products are to be regulated by UNBS.

The Committee further observes that, notwithstanding the Cabinet position, the Bill should clearly provide for coordination between the Authority and the Uganda National Bureau of Standards so as to avoid duplication of mandates, multiple licensing requirements and unnecessary compliance burdens on persons dealing in cosmetic products. The Committee also noted that cosmetic products that contain

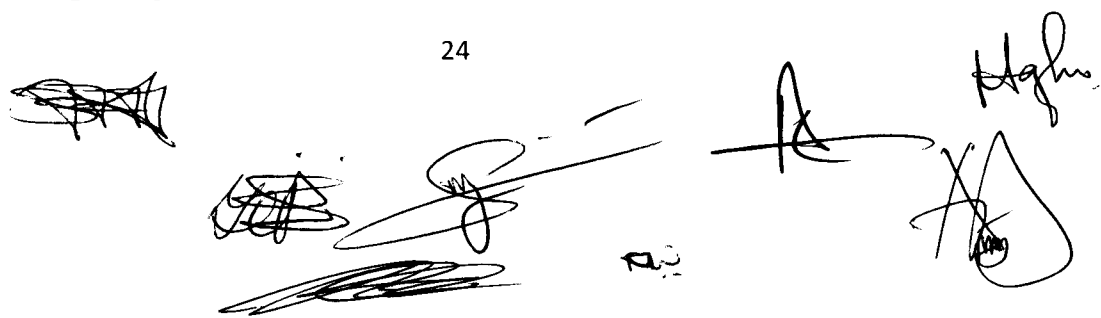
Recommendation

- The Committee recommends that the provisions on the regulation of cosmetic products be retained, in line with the Cabinet decision authorising the Authority to regulate cosmetic products while UNBS retains the mandate of custodianship, in order to avoid double regulation, promote regulatory clarity and strengthen consumer protection.

Clause 70-75. Categories of public health products

Observation

The Committee notes that the Bill provides for the regulation of public health products through registration, notification, listing, import and export licensing,



distribution licensing, licensing of premises, and reporting of defects and adverse reactions. The Committee further notes concern about possible double regulation with the Uganda National Bureau of Standards, but observes that this was resolved by the Cabinet Memorandum which authorised the Authority to regulate public health products in order to avoid duplication and regulatory uncertainty.

Recommendation

The Committee recommends that the provisions be retained and clarified to affirm the Authority as the lead regulator of public health products, while providing for coordination with the Uganda National Bureau of Standards on standards-related matters only.

Clauses 76-81 Nutritional supplements

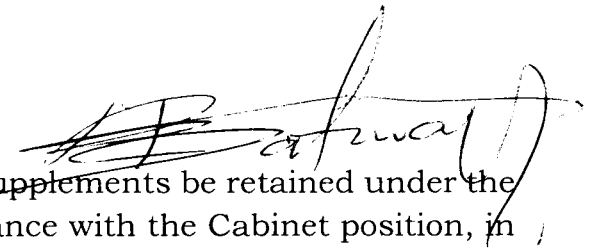
Observation

The Committee notes that the Bill brings nutritional supplements within the regulatory mandate of the Authority by providing for registration, notification, listing, import and export licensing, distribution licensing, licensing of premises, and reporting of defects and adverse reactions. The Committee observes that this is necessary to promote oversight over products that are increasingly consumed by the public and that may pose risks to health where they are of poor quality, unsafe, misleadingly labelled, or improperly distributed.

The Committee further notes that concerns were raised regarding possible duplication of mandates between the Authority and the Uganda National Bureau of Standards, particularly in relation to standards, quality control and market oversight for nutritional supplements. The Committee, however, notes that this matter was resolved through a Cabinet Memorandum which authorised the Authority to regulate nutritional supplements, in order to avoid double regulation and provide a clear institutional mandate.

The Committee therefore observes that the regulation of nutritional supplements under the Bill is justified, but the law should clearly delineate the role of the Authority vis-à-vis that of the Uganda National Bureau of Standards, so as to avoid overlap, regulatory uncertainty and unnecessary compliance burdens on operators.

Recommendation



The Committee recommends that nutritional supplements be retained under the regulatory mandate of the Authority in accordance with the Cabinet position, in order to provide a clear and single regulatory framework and avoid double regulation.

Clause 83. Conformity to standards of the Uganda National Bureau of Standards Act

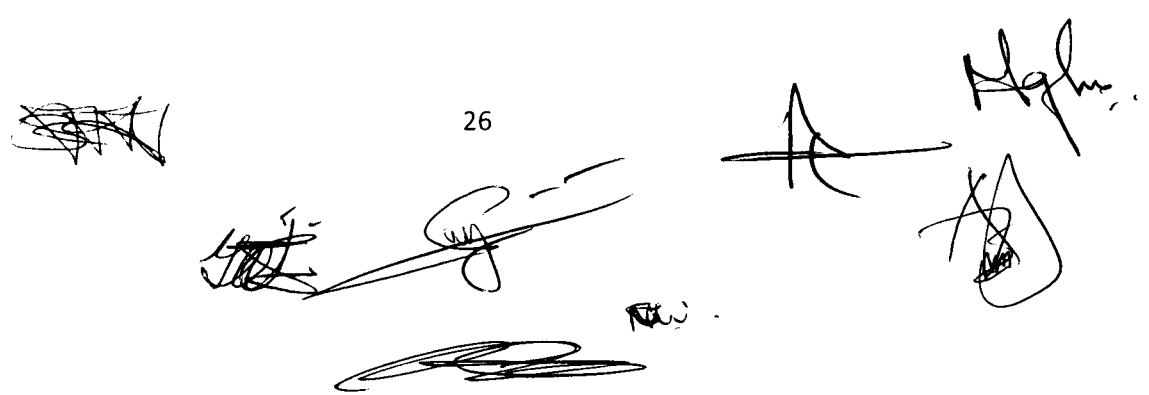
Observation

The Committee notes that the Uganda National Bureau of Standards is the national institution mandated to develop, promote and enforce standards for commodities in Uganda. The Committee further notes, however, that in respect of products regulated under this Act, the Cabinet Memorandum adopted a policy position that the regulatory control of such products should fall under the Authority, while the custodianship of national standards remains with the Uganda National Bureau of Standards.

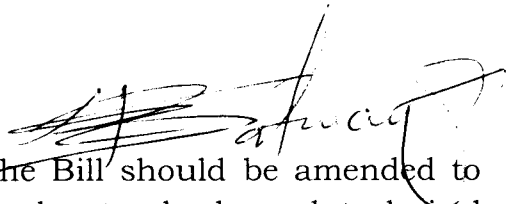
The Committee observes that this policy position is intended to avoid duplication of mandates and to establish a coherent regulatory framework for drugs and other regulated products under the Bill. The Committee nevertheless notes that unless the Bill clearly delineates the respective roles of the Authority and the Uganda National Bureau of Standards, there is a risk of overlap, uncertainty and operational conflict in the formulation, adoption, application and enforcement of standards relating to products regulated under the Act.

Recommendation

- The Committee recommends that given the technical and sector-specific nature of drugs, medical devices, cosmetics, nutritional supplements and public health products, the Authority should take the lead in formulating standards and technical requirements applicable to products under the Act, while the Uganda National Bureau of Standards should retain its overarching mandate as custodian of national standards. This approach would preserve the institutional role of the Uganda National Bureau of Standards, while recognising the specialised regulatory competence of the Authority in matters falling within its mandate.



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- The Committee therefore recommends that the Bill should be amended to empower the Authority to formulate and apply standards and technical requirements for products regulated under the Act, while UNBS remains the national custodian of standards and collaborates with the Authority in their harmonisation and publication.

Clause 122. Regulation of veterinary drugs, veterinary medical devices and field trials.

Observation

The Committee notes that the Bill extends regulation to veterinary drugs, veterinary medical devices and field trials relating to veterinary products, pending the enactment of a specific law by Parliament to regulate those matters. The Committee observes that this is a necessary transitional measure intended to prevent a regulatory gap in relation to products that directly affect animal health, public health and food safety being that these have been under regulation by the National Drug Policy and Authority Act and the Food and Drug Act which Acts are being repealed by the Bill.

The Committee further notes that veterinary drugs and veterinary medical devices, like human health products, require oversight to ensure their safety, quality and efficacy, and that field trials involving such products must be conducted within a regulated framework in order to safeguard animal welfare, public health and the environment. In the absence of an express legal framework governing these matters, the Committee appreciates clause 122 of the Bill in providing an interim regulation so that these products and activities do not remain outside effective control.

The Committee, further, observes that the regulation of veterinary products and veterinary field trials under the Bill should be clearly framed as an interim arrangement, pending the enactment of a dedicated law by Parliament. This is important in order to maintain clarity of legislative purpose, avoid institutional overlap, and recognise that veterinary regulation involves sector-specific considerations that may require a more comprehensive framework tailored to animal health and veterinary practice.

Recommendation

- The Committee recommends that the Bill should retain the interim regulation of veterinary drugs, veterinary medical devices and veterinary field trials, pending the enactment of a specific law by Parliament.

- The Committee further recommends that the Bill should clearly state that this regulatory mandate is transitional in nature and shall apply only until Parliament enacts a law specifically governing veterinary drugs, veterinary medical devices and related field trials. This will ensure continuity of regulation while preserving the need for a specialised legislative framework for veterinary products and activities.

8.0 Conclusion

The Committee is of the considered opinion that the National Drug and Health Products Authority Bill presents a timely opportunity to modernise Uganda’s regulatory framework for drugs and health products in line with international best practices. The Bill has the potential to strengthen public health protection, support local pharmaceutical production, promote innovation, improve investor confidence and create a more predictable regulatory environment.

However, the Committee also notes that a number of provisions require amendment in order to make the law practical, fair, efficient and responsive to Uganda’s economic, institutional and social realities. In particular, the Bill should better safeguard regulatory independence, reduce duplication with other agencies, provide for a more efficient appeals process, accommodate traditional and complementary medicine, strengthen the framework on antimicrobial resistance, streamline licensing and better support innovation and investment.

The Committee therefore recommends that Parliament do pass the Bill subject to the proposed amendments and recommendations contained in this Report.

Rt. Hon. Speaker and Hon. Members, I beg to report.

PROPOSED AMENDMENTS TO THE NATIONAL DRUG AND HEALTH PRODUCTS BILL, 2025

CLAUSE 2. INTERPRETATION

Clause 2 is amended—

(a) in the definition of “adverse event”, by substituting for the word “unpleasant”, the word “unintended”;

(b) by substituting for the definition of “adverse reaction”, the following—

“adverse reaction” means any noxious or unintended response to a drug, cosmetic product, public health product, nutritional supplement or medical device, occurring at a dose normally used in a human for prophylaxis, diagnosis or therapy, including use outside the marketing authorisation, where there is a reasonable possibility of a causal relationship between the product and the response”;

(c) in the definition of “authorised pharmacopoeia” by inserting immediately after the word “means”, the words “any pharmacopoeia recognised by the Authority, including”;

(d) in the definition of “biologicals” by inserting immediately after the word “includes” the word “vaccines”;

(e) in the definition of “cosmetics” by inserting immediately after paragraph (f), paragraphs providing for “glutathione”, “kojic acid”, “salicylic acid”, or “alpha hydroxy acid”;

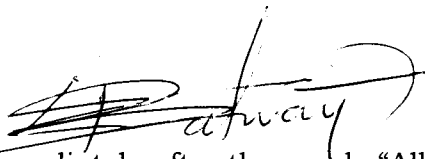
(f) in the definition of “drug”—

(i) by inserting immediately after the word “used”, the words “or intended to be used”; and

(ii) in paragraph (c), by deleting the word “gene therapy”;

(g) in the definition of “health care professional”—

(i) by deleting the word “care”; and



- (ii) by inserting immediately after the words “Allied Health Professionals Act” the words “or any other recognised professional regulatory body”;
- (h) in the definition of “lot release”, by substituting for the word “medicines” the word “diagnostics”;
- (i) in the definition of “medical device” in paragraph (b) by inserting immediately after the word “disinfection” the words “cleaning or sterilisation”;
- (j) by inserting in the appropriate alphabetical order, the following—

“adulterated” means a drug, medical device, cosmetic product, public health product, or nutritional supplement which is contaminated or unsafe for human consumption, or manufactured, prepared, packed, stored, transported or distributed under unsanitary conditions, or contains any harmful or unauthorised substance, or has been substituted, diluted or otherwise treated in a manner that reduces its quality, purity, safety or efficacy or renders it injurious to health;

“compassionate use” means the use of an unregistered drug or a drug under clinical investigation which is not a clinical trial, for the treatment of a patient suffering from a serious or life-threatening condition where no satisfactory registered prevention or treatment is available in Uganda;

“falsified” means a drug, medical device, cosmetic product, public health product, or nutritional supplement which deliberately misrepresents the identity, composition or source of the drug, medical device, cosmetic product, public health product, or nutritional supplement;

“manufacture or manufacturing” includes all operations of receipt of materials, production, processing, packaging, repackaging, labelling, relabelling, quality control, release or storage and related controls of drugs, medical devices, cosmetic products, public health products and nutritional supplements;

“Ministry” means the Ministry responsible for health;

“not fit for intended purpose” means a regulated product which—

- (a) is malfunctional;
- (b) in not safe or efficacious:
- (c) does not meet the quality prescribed under this Act; or
- (d) is expired;”

“substandard” means a drug, medical device, cosmetic product, public health product, or nutritional supplement which is not of the nature, substance, quality or specifications, prescribed under this Act.”



Justification

- The substitution of the word “adverse reaction” is to align the provision with internationally recognised regulatory standards on the definition of the word.
- The amendment of the word “drug” is to cater for intended use of drugs.
- The insertion of the new terms in the Bill is to define the meaning of the terms for clarity and to remove ambiguity in the interpretation of the terms.

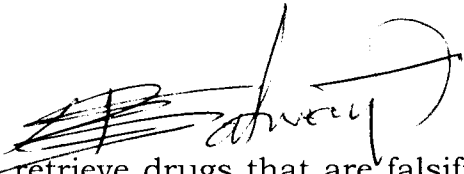
CLAUSE 5. FUNCTIONS OF THE AUTHORITY

Clause 5 is amended—

- (a) in sub clause (1)—
 - (i) in paragraph (a)(iii), by deleting the word “unwholesome” and wherever it appears in the Bill;
 - (ii) in paragraph (a)(vii), by deleting the words “for vaccines, biologicals and diagnostics”; and
 - (iii) in paragraph (b)(iv), by inserting immediately after the words “medical devices”, the words “cosmetic products, public health products and nutritional supplements”;
 - (iv) by inserting immediately after paragraph (b)(vi), the following—
“to prescribe standards for medical devices, cosmetic products, public health products, and nutritional supplements.”
- (b) in sub clause (2), by inserting immediately after the word “nutritional supplements”, the words “in accordance with this Act, and any other applicable law”;
- (c) in sub clause (4)—
 - (i) in paragraph(b), by inserting immediately after the word “guidelines”, the words “in accordance with this Act, and any other applicable law”; and
 - (ii) in paragraph (d), by inserting immediately after the word “nutritional supplements”, the words “in accordance with this Act, and any other applicable law”.

Justification

- To empower the Authority to retrieve drugs that are falsified, adulterated, substandard, or expired.
- To empower the Authority to regulate premises where drugs are analysed, tested and researched.
- For consistency in referring to the different products being regulated under the Bill.



Justification

- To empower the Authority ~~to~~ retrieve drugs that are falsified, adulterated, substandard, or expired.
- To empower the Authority to regulate premises where drugs are analysed, tested and researched.
- For consistency in referring to the different products being regulated under the Bill.
- To provide for compliance with relevant laws.

CLAUSE 6. DIRECTIONS OF THE MINISTER

Clause 6 is amended by substituting for sub clause (2), the following—

“The directions given by the Minister under subsection (1) shall not adversely affect or interfere with the independence of the Authority, or the performance of the functions and exercise of the powers of the Authority under this Act.”

Justification

- The amendment clarifies that ministerial directions are of a general policy nature and shall not undermine the statutory independence of the Board in the discharge of its functions and powers.

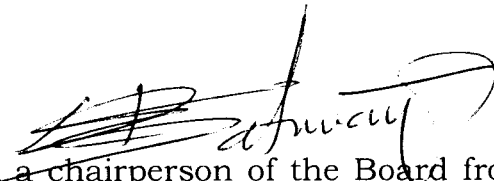
CLAUSE 7. BOARD OF DIRECTORS

Clause 7 is substituted for the following—

“7. Board of Directors

- (1) The Authority shall have a Board which shall be the governing body of the Authority.
- (2) The Board shall consist of seven members appointed by the Minister.
- (3) A member of the Board shall be a person of high moral character and proven integrity, with qualifications and experience in the field of pharmacy, medicine, law, financial management, traditional and complementary medicine, investigations, biomedical engineering, nutrition, cosmetology, bioethics, consumer protection or public health.





(4) The Minister shall appoint a chairperson of the Board from among the members of the Board.

(5) At least a third of the members of the Board shall be women.”

Justification

- The Bill expands the mandate of the Authority beyond pharmaceuticals to include medical devices, cosmetic products, nutritional supplements and health products, each of which presents distinct technical and safety considerations requiring specialised oversight.
- It is necessary that the Board collectively possess expertise in the regulated products to ensure effective governance, informed decision-making and proper supervision of the Authority’s regulatory functions.
- The clause on gender is to align the Bill with the constitutional policy of the State taking affirmative action in favour of women as a marginalised group.

CLAUSE 8. TENURE OF OFFICE OF MEMBERS OF THE BOARD

Clause 8 is amended—

(a) by substituting for sub clause (1), the following—

“(1) A member of the Board shall hold office for four years and is eligible for re-appointment for one more term only.”

(b) by inserting immediately after sub clause (1), the following—

“A member of the Board shall hold office on terms and conditions specified in his or her instrument of appointment.”

(c) by inserting immediately after sub clause (3), the following—

“The Minister shall fill a vacancy on the Board in accordance with the procedure prescribed by regulations made under this Act.”

Justification



- The re-arrangement of sub clause (1) is for clarity and to provide a definite term of office for Board members to strengthen accountability, enhance performance, while allowing for reappointment based on merit and performance.
- The new insertion is to obligate the Minister to fill a vacancy within the stipulated timelines under regulations to ensure efficiency in the functioning of the Board.

CLAUSE 10. SECRETARIAT

Clause 10 is amended in sub clause (1) by substituting for the word “supervision”, the word “control.”

Justification

- To reflect the proper governance role of the Board. The Board exercises strategic authority and overall control over the affairs of the Authority while the Executive Director exercises supervision relating to day-to-day administrative oversight over the Secretariat.

CLAUSE 11. EXECUTIVE DIRECTOR

Clause 11 is amended—

(a) by substituting for sub clause (1), the following—

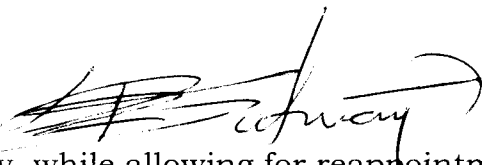
“(1) The Secretariat shall be headed by an Executive Director who shall be appointed by the Board for a term of five years and is eligible for re-appointment for one more term only.”

(b) by inserting immediately after sub clause (1), the following—

“(2) The Executive Director shall hold office on terms and conditions specified in his or her instrument of appointment.”

Justification

- The introduction of a limitation of the Executive Director’s term is to strengthen accountability, enhance performance, and provide orderly



leadership transition within the Authority, while allowing for reappointment based on merit and performance.

CLAUSE 12. STAFF OF THE AUTHORITY

Clause 12 is amended in sub clause (3), by deleting the words “and the discipline of the Executive Director and”.

Justification

- For clarity since the clause is providing for regulation of the terms and conditions of service for the other employees of the Authority, including discipline of the Executive Director would cause confusion.

CLAUSE 13. RULES TO REGULATE STAFF

Clause 13 is amended by deleting the words “in conformity as may be applicable with the Uganda Public Service Standing Orders.”

Justification

- To remove ambiguity by enabling the Authority to make internal staff rules appropriate to its functions, while remaining subject to the Act and other applicable laws.

CLAUSE 20. ANNUAL REPORT

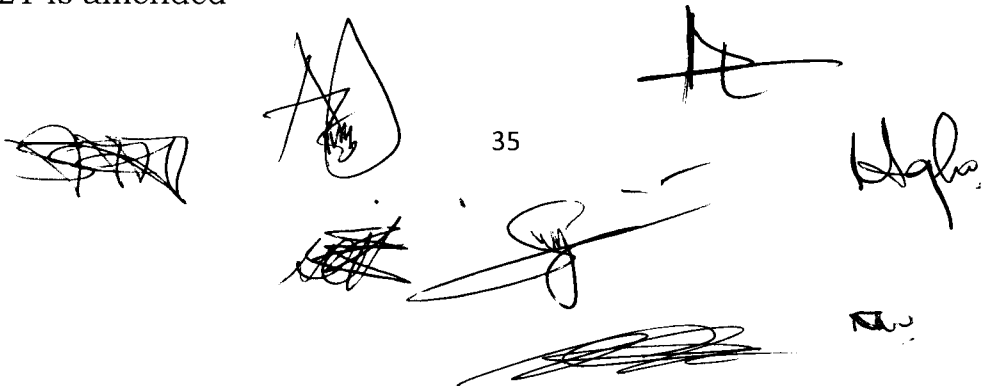
Clause 20 is amended in sub clause (1), by substituting for the words “as soon as practicable but not less later than six months”, for the words “within three months”.

Justification

- To promote timely reporting and enhance accountability by requiring submission of the annual report within three months after the end of the financial year.

CLAUSE 21. REGISTRATION, NOTIFICATION AND LISTING OF DRUGS

Clause 21 is amended—



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- (a) in sub clause (1), by inserting immediately after the word “notified”, the word “listed”.
- (b) by substituting for sub clause (3), the following—

“Notwithstanding subsection (1), the Authority may for a specified purpose, and subject to conditions the Authority may deem fit, authorise the manufacture, importation, exportation, distribution, supply or dispensation of a drug which is not registered, notified or listed by the Authority—

- (a) where the drug is required by the Authority for purposes of registration, notification or listing of the drug under this Act;
- (b) where the drug is required for purposes of conducting a clinical trial;
- (c) with respect to importation, where the drug is imported for personal use;
- (d) where the drug is required for compassionate use;
- (e) where the drug is required under extraordinary circumstances as may be prescribed in regulations made under this Act; or
- (f) where the drug is required for approved scientific education and research.”

(c) in sub clause (8)—

n paragraph (a), by substituting for the words “three thousand”, the words “ten thousand”; and

n paragraph (b), by substituting for the words “five hundred”, the words “five thousand”.

Justification

- The amendment for listing as an additional regulatory mechanism is to ensure that drugs which may not be subject to full registration are still brought under the supervision of the Authority. Listing facilitates market oversight, traceability and enforcement, while allowing a proportionate regulatory approach.
- The exemption on grounds of “compassionate use” allows timely access to drugs in exceptional cases of unmet medical need where the ordinary registration or notification process may cause harmful delay and the person is suffering from a life-threatening disease.

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- The insertion of a provision for an application for the exemption to be prescribed by regulation preserves regulatory control of the conditions and procedure by the Authority.

CLAUSE 22. LICENCE FOR THE MANUFACTURE OF DRUGS

Clause 22 is amended in sub clause (5) (b), by substituting for the words “five years”, the words “ten years”.

Justification

- To enhance the penalty for the manufacture of drugs without a licence issued under this Act.

CLAUSE 23. LICENCE FOR THE DISTRIBUTION OF DRUGS

Clause 23 is amended in sub clause (6)—

(a) in paragraph (a), by substituting for the words “five thousand”, the words “ten thousand”; and

(b) in paragraph (b), by substituting for the words “five years”, the words “ten years”.

Justification

- To enhance the penalty for distribution of drugs without a licence.

CLAUSE 24. LOT RELEASE OF VACCINES, BIOLOGICALS AND DIAGNOSTICS

Clause 24 is substituted for the following—

“24. Lot release by the Authority

(1) The Authority shall establish and maintain a system of lot release of biologicals, vaccines, diagnostics and other medicinal products.

(2) A person shall not release on the market a biological, vaccine, diagnostic or medicinal product unless the person has been issued with a certificate of lot release by the Authority.

- (3) A person who intends to release a biological, vaccine, diagnostic or medicinal product on the market shall, upon payment of the prescribed fee, apply to the Authority for a certificate of lot release.
- (4) The Authority shall grant a certificate of lot release to a person who satisfies the requirements and conditions prescribed by regulations made under this Act, and may impose such conditions on the certificate as the Authority may consider appropriate.
- (5) A person who contravenes this section commits an offence and is liable on conviction—
 - (a) in case of a corporate body, to a fine not exceeding ten thousand currency points; and
 - (b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.”

Justification

- The substitution is to ensure clarity that the lot release system is to be established by the Authority.
- To prescribe the process of applying for a certificate of lot release.

CLAUSE 25. IMPORTATION OF DRUGS

Clause 25 is amended—

- (a) in sub clause (2) by—
 - (i) substituting for the words “which is not registered”, the words “without a licence.”
 - (ii) inserting immediately after paragraph (d), the following—
 - “(e) purposes of compassionate use;
 - (f) extra ordinary circumstances as may be prescribed in regulations made under this Act;
 - (g) approved scientific education and research.”
- (b) by deleting sub clause (6) and (7).

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(c) in sub clause 8 (b) by—

- (i) substituting for the word “re-export”, the word “return”; and
- (ii) substituting for the word “import”, the word “export”.

(d) by inserting immediately after sub clause (9), the following—

“A person who imports a drug contrary to this section commits an offence and is liable on conviction—

(a) in case of a body corporate, to a fine not exceeding ten thousand currency points; and

in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.”

Justification

- To cater for situations of compassionate use of drugs and academic research purposes.
- To establish legal responsibility for owners of vessels or vehicles to critically inquire into legality of drugs transported on their vessels.
- To provide for punishment as a way of deterring importation of drugs contrary to the provisions of the section.

CLAUSE 26. IMPORTATION OF DRUGS FOR DONATION

Clause 26 is amended in sub clause (5)—

(a) in paragraph (a), by substituting for the words “three thousand”, the words “five thousand”.

(b) in paragraph (b), by substituting for the words “five hundred”, the words “three thousand”.

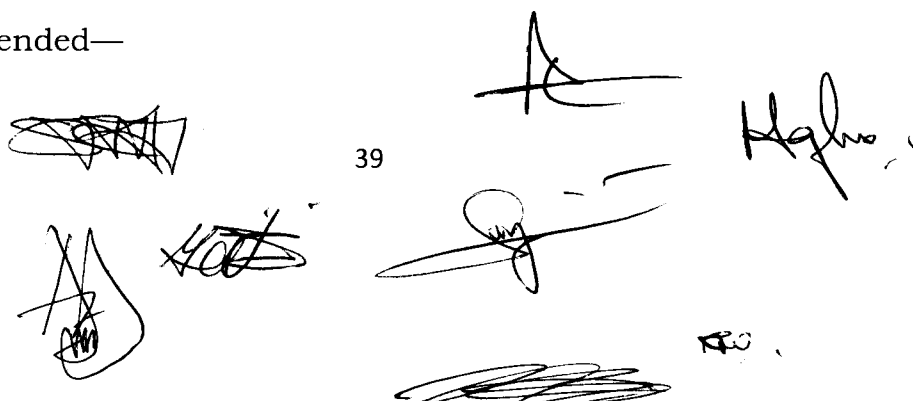
Justification

To enhance the penalty for importation of drugs for donation in contravention of the Act.

CLAUSE 28. OPERATION OF WHOLESALE OR RETAIL PHARMACY

Clause 28 is amended—

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(a) in the headnote by deleting the words “wholesale or retail”

(b) by inserting immediately after sub clause (5), the following—

“(6) An application for a licence to operate a pharmacy under this section shall specify the location of the pharmacy, and shall comply with the minimum distance requirements prescribed by regulations made under this Act.

(c) in sub clause (6) —

(i) in paragraph (a) by substituting for the words “five thousand”, the words “ten thousand”.

(ii) in paragraph (b) by substituting for the words “five hundred”, the words “five thousand”.

Justification

- To empower the Authority to regulate all forms of pharmacies.
- To provide a clear statutory basis for the Authority to consider the location of proposed pharmacy premises at the point of application and to enforce minimum distance requirements through regulations.
- It also promotes orderly distribution of pharmacies, avoids undue clustering of outlets, and supports equitable access to pharmaceutical services.

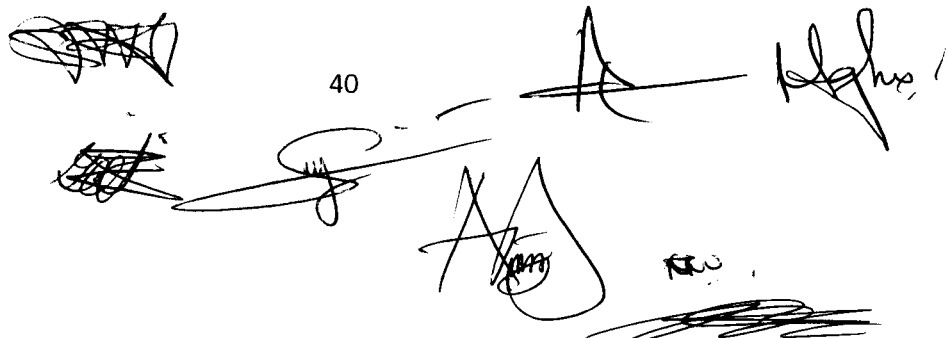
CLAUSE 30. INSPECTION OF PREMISES BY THE AUTHORITY

Clause 30 is amended by inserting immediately after sub clause (3), the following—

“The requirements for issuance of certificate of suitability of premises shall be prescribed by regulations made under this Act.”

Justification

- The proposed insertion provides a legal basis for prescribing the requirements for the issuance of a certificate of suitability of premises through regulations.



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- It will also allow the Authority to establish clear and flexible technical standards for premises used in regulated activities, while ensuring updates to reflect evolving regulatory and safety standards.

CLAUSE 34. PACKAGING AND LABELLING OF DRUGS

Clause 34 is amended by inserting immediately before sub clause (1), the following—

“A manufacturer, importer, exporter, distributor or supplier of a drug shall cause the label of each drug to bear a unique identifier for purposes of traceability, as may be prescribed by regulations made under this Act.”

Justification

- The amendment introduces a unique identifier for each drug which strengthens traceability for recalls, pharmacovigilance, and enforcement against diversion and counterfeits.

CLAUSE 35. CLASSIFICATION OF DRUGS

Clause 35 is amended—

(a) in sub clause (1)—

(a) by substituting for paragraph (a), the following—

“Class AI drugs; narcotic drugs and psychotropic substances, which shall only be dispensed on the prescription of a medical practitioner or dental practitioner for medical or dental purposes and which shall be dispensed by a pharmacist;”

(b) by substituting for paragraph (b), the following—

“Class AII drugs; other prescription-only drugs, which shall only be dispensed on the prescription of a medical practitioner or dental practitioner for medical or dental purposes and which shall be dispensed by a pharmacist;”

(c) by substituting for paragraph (c), the following—

41

“Class B drugs; drugs which may be dispensed by a pharmacist without a prescription of a medical practitioner or dental practitioner;

(b) by inserting immediately after sub clause (2), the following—

“A person who dispenses any drug contrary to this section, commits an offence and shall be liable, on conviction, to a fine not exceeding three thousand currency points or imprisonment not exceeding five years, or both.”

Justification

- To create a penalty provision to backstop compliance. Without an express penalty, enforcement is weak and deterrence is minimal for such a high-risk area.
- Clear penalties improve prosecutorial certainty and consistent punishment.

CLAUSE 36. POSSESSION OF DRUGS

Clause 36 is amended in sub clause (4) by inserting immediately before the words “any person”, the words “subject to the Narcotic Drugs and Psychotropic substances (Control) Act”.

Justification

- To align the penalty under the Act with the penalty under the Narcotic Drugs and Psychotropic substances (Control) Act.

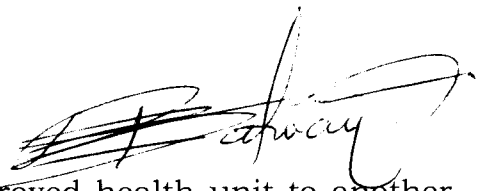
CLAUSE 37. NEED FOR PRESCRIPTION FOR RESTRICTED DRUGS

Clause 37 is amended by substituting for subclause (6), the following—

“(6) Subsection (1)(a) shall not apply where the drug is supplied or dispensed—

- (a) whether personally or on a signed order—
 - (i) to a medical practitioner, dental practitioner or pharmacist; or
 - (ii) to a pharmacy for the purpose of the drug being subsequently supplied or dispensed, or used for approved scientific education or research.

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(b) from a dispensing department of an approved health unit to another department for purposes of the drug being subsequently supplied or dispensed in accordance with regulations made under this Act.”

Justification

- The insertion of medical practitioner and dental practitioner is to cater for all the different personnel who are authorized under the Act to dispense class AI and AII drugs.
- To cater for and allow legitimate institutional supply chains that operate on purchase orders rather than individual prescriptions.
- To align research procurement to the waiver mechanism so that research access does not undermine prescription controls.

CLAUSE 38. SUPPLY, DISPENSING AND MIXING OF RESTRICTED DRUGS BY NURSES, MIDWIVES AND DISPENSERS

Clause 38 is amended—

- (a) in the headnote by deleting the words “mixing”;
- (b) in sub clause (2)(b)(ii) by substituting for the word “ingredient” the word “drug”; and
- (c) by deleting sub clauses (4) and (5).

Justification

- The deletion of ingredient is because the dispenser under this clause is not obliged to know the ingredients in the drug dispensed.
- The practice of mixing and compounding drugs is no longer done at that level of health care provision.

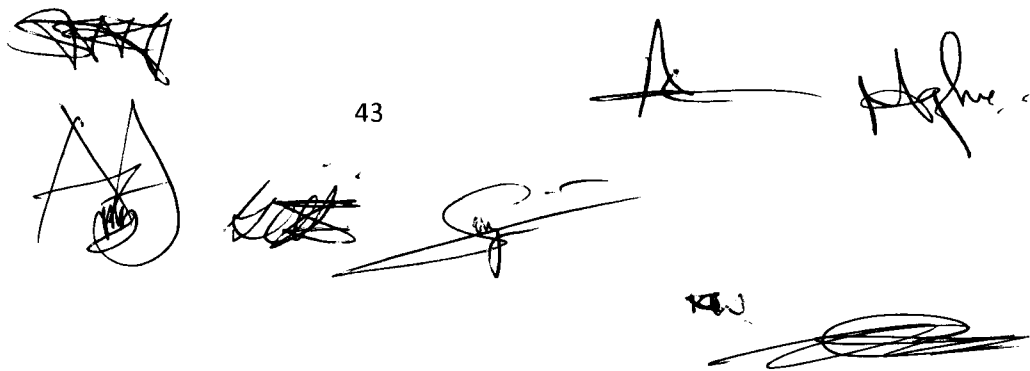
CLAUSE 39. PROMOTION OF DRUGS

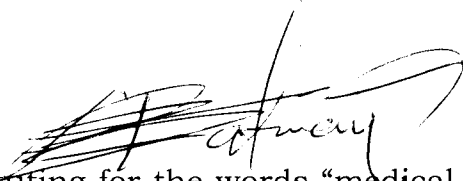
Clause 39 is deleted.

Justification

- Promotion is regulated alongside advertisement under clause 46 of the Bill therefore it would be repetitive.

CLAUSE 40. LOSS OF CLASS AI DRUGS AND CLASS AII DRUGS





Clause 40 is amended in sub clause (1) by substituting for the words “medical practitioner, dental practitioner or pharmacist”, the words “A pharmacist or an authorised person registered or enrolled under the Nurses and Midwives Act or the Allied Health Professionals Act”

Justification

The amendment is consequential to the amendments in clause 35 and 38.

CLAUSE 44. WITHDRAW OF DRUGS

Clause 44 is amended in sub clause (2) by deleting the words “and on its own decision”.

Justification

To avoid repetitions and redundant use of words.

CLAUSE 45. DECEPTION OF CONSUMERS.

Clause 45 is amended in sub clause (3)—

- (a) in paragraph (a), by substituting for the words “ten thousand”, the words “one hundred fifty thousand”; and
- (b) in paragraph (b) by substituting for the words “five thousand”, the words “twenty thousand, and the words “five years” the words “fifteen years”.

Justification

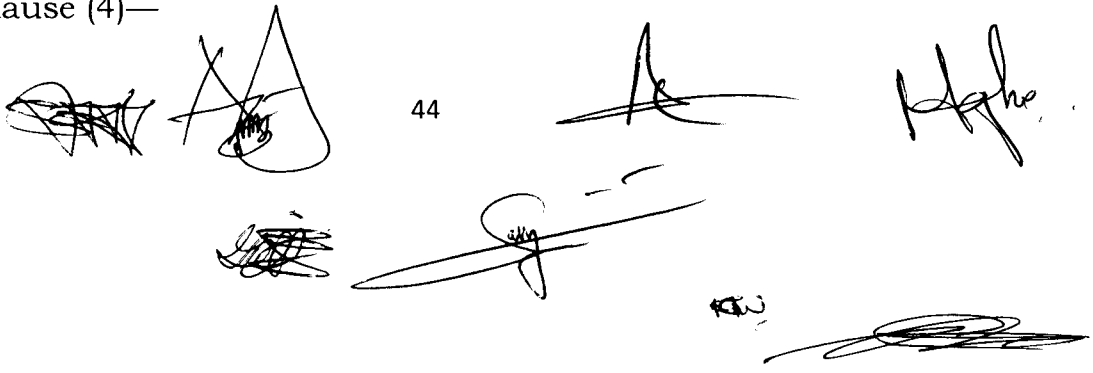
- The amendment in sub clause (3) is to enhance the punishment since wrong advertisement of regulated products could mislead consumers to make uninformed decisions which could lead to fatal results.

CLAUSE 46. ADVERTISEMENT OF DRUGS

Clause 46 is amended—

- (a) in sub clause (2) by inserting a new paragraph immediately after paragraph (c) as follows—
“giving free samples, sponsorship or promotion of a drug,”

- (b) in sub clause (4)—





- (i) in paragraph (a) by substituting for the words “five thousand”, the words “one hundred and fifty thousand”; and
- (ii) in paragraph (b) by substituting for the words “three hundred”, the words “twenty thousand”, and for the words “five years”, the words “fifteen years”.

Justification

- To enhance the punishment since false advertisement of drugs directly affects the decisions of consumers and consumption of drugs based on false advertisement could lead to fatal results.

CLAUSE 47. MANUFACTURE, DISTRIBUTION, IMPORTATION, EXPORTATION, SUPPLY AND DISPENSING OF FALSIFIED DRUGS PROHIBITED

Clause 47 is amended in sub clause (5)—

- (a) in paragraph (a), by substituting for the words “twenty thousand”, the words “one hundred and fifty thousand”; and
- (b) in paragraph (b), by substituting for the words “five thousand”, the words “twenty thousand”.

Justification

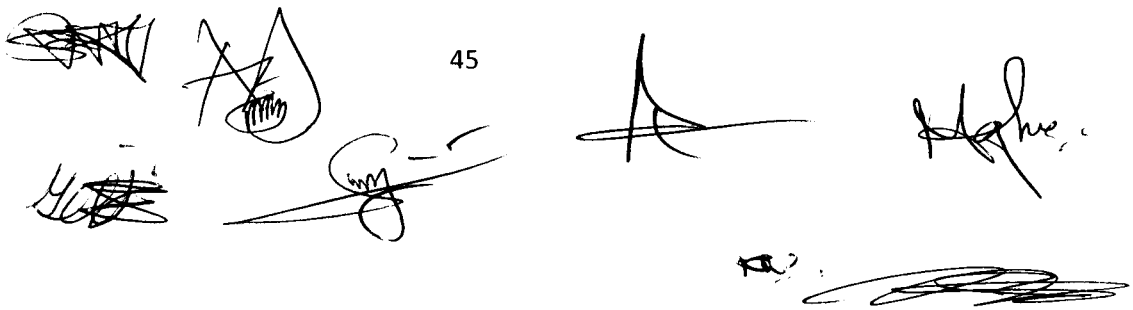
- To enhance the punishment since falsification of drugs directly affects the decisions of consumers and consumption of such products could lead to fatal results.

CLAUSE 48. SUPPLY OR DISPENSING OF SUBSTANDARD DRUGS PROHIBITED

Clause 48 is amended—

- (a) by deleting sub clause (4);
- (b) in sub clause (5)—
 - (i) in paragraph (a), by substituting for the words “five thousand”, the words “one hundred and fifty thousand”; and

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(ii) in sub clause (b), by substituting for the words “three thousand” the words “twenty thousand”, and for the words “five years”, the words “fifteen years”.

Justification

- The deletion of the definition of “not fit for intended purpose” in sub clause (4) is to avoid repetition since the term is defined in the interpretation section.
- To enhance the punishment since deception of consumers directly affects the decisions of consumers and consumption of such products could lead to fatal results.

CLAUSE 50. AUTHORISATION TO CONDUCT CLINICAL TRIALS

Clause 50 is amended —

- (a) in the headnote by inserting immediately after the words “clinical trials”, the words “for drugs”;
- (b) in sub clause (1), by inserting immediately after the words “clinical trial”, the words “for a drug”;
- (c) in sub clause (2), by substituting for the words “field trial” appearing at the end of the clause, the words “clinical trial”.
- (d) by inserting immediately after sub clause (9), the following—

“This section shall not apply to a clinical trial of a drug conducted by the Ministry in public interest.

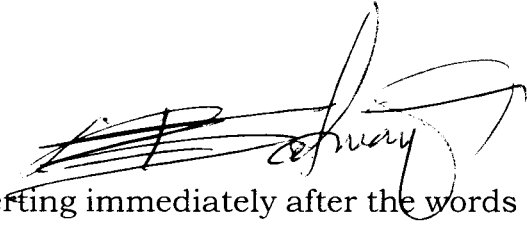
Notwithstanding subsection (9), the Ministry shall, while conducting a clinical trial of a drug, conduct the clinical trial in accordance with good clinical practices prescribed by regulations made under this Act.”

Justification

- To facilitate the seamless execution of the mandate of the Ministry of Health.
- For clarity since the clause is on clinical trial and not field trial.

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CLAUSE 51. GOOD CLINICAL PRACTICES



Clause 51 is amended in sub clause (1), by inserting immediately after the words “clinical trial”, the words “for a drug”.

Justification

It is a consequential amendment.

CLAUSE 52. OBLIGATION FOR MANUFACTURERS ETC. TO ESTABLISH PHARMA-COVIGILANCE SYSTEMS

Clause 52 is amended—

(a) by substituting for sub clause (2), the following—

“The Authority may, where it deems necessary, request the person referred to in sub section (1) to conduct for the drugs, a safety study, an efficacy study, or both.”

(b) by inserting immediately after sub clause (3), the following—

“The Authority shall, upon approval of the pharmacovigilance system, issue a certificate of good manufacturing practices.”

Justification

- To introduce grant of a certificate upon approval of a pharmacovigilance system.

CLAUSE 53. OBLIGATION OF HEALTH CARE PROFESSIONALS TO REPORT ADVERSE REACTIONS AND ADVERSE EVENTS OF DRUGS

Clause 53 is amended by deleting the word “care” wherever the word appears in the phrase “health care professional”, and wherever it appears in the Bill.

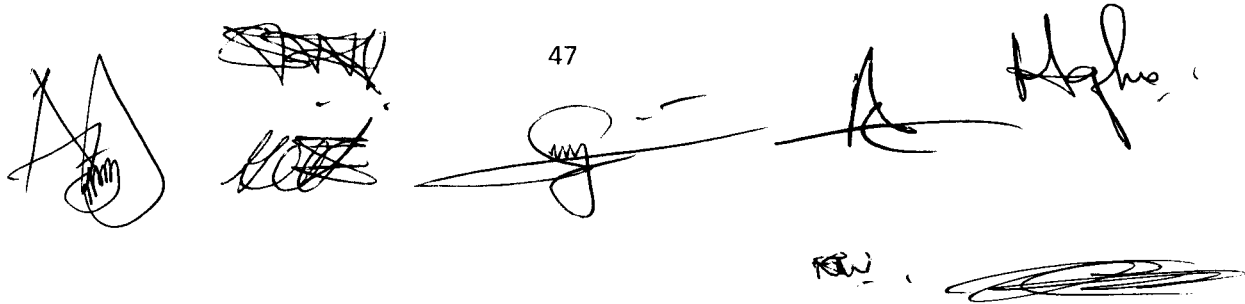
Justification

- The word health care professional is not a recognised expression in the health sector.

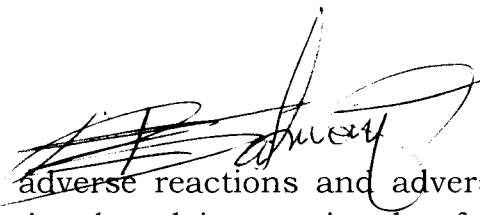
CLAUSE 54. PHARMACOVIGILANCE BY THE AUTHORITY

Clause 54 is substituted for the following—

“(1) The Authority shall establish a pharmacovigilance system for monitoring and analysing the adverse reactions and adverse events of a drug.



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(2) The Authority shall share information on adverse reactions and adverse events and remedial action taken with regional and international safety monitoring systems.”

Justification

- To create an obligation for the Authority to establish a mechanism of receiving information on adverse reactions and adverse events since the Authority is not involved in actual management of patients.

CLAUSE 56. REGISTRATION, NOTIFICATION AND LISTING OF MEDICAL DEVICES

Clause 56 is amended by substituting for sub clause (2), the following—

“(2) Notwithstanding subsection (1), the Authority may for a specified purpose, and subject to conditions the Authority may deem fit, authorise the manufacture, distribution, importation, exportation or supply by wholesale or retail of a medical device which is not registered, notified or listed by the Authority—

- (a) where the medical device is required by the Authority for purposes of registration, notification or listing of the drug under this Act;
- (b) where the medical device is required for purposes of conducting a clinical trial;
- (c) with respect to importation where the medical device is imported for personal use;
- (d) where the medical device is required for compassionate use;
- (e) where the medical device is required under extra ordinary circumstances as may be prescribed in regulations made under this Act; or
- (f) where the medical device is required for approved scientific education and research.”

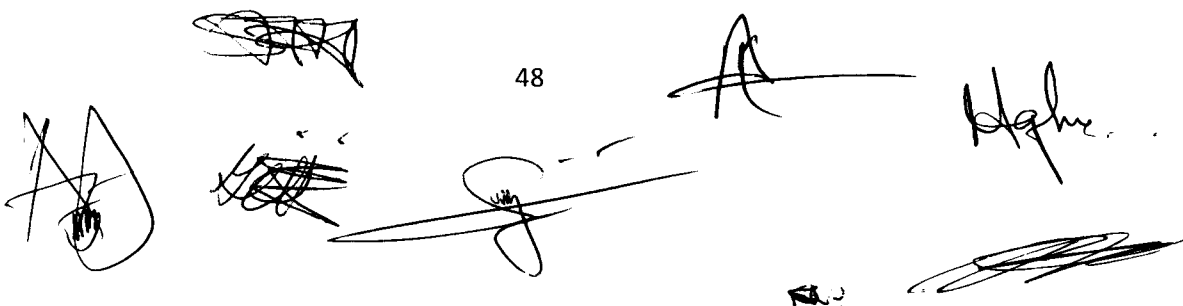
Justification

For consistency in having similar exemptions.

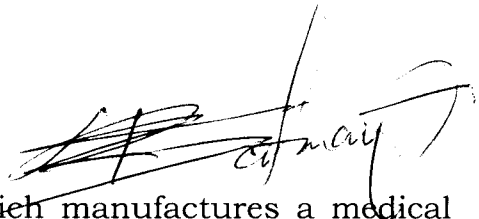
CLAUSE 57. LICENCE FOR THE MANUFACTURE OF MEDICAL DEVICES

Clause 57 is amended in sub clause (5)(a) by substituting for the words “five thousand”, the words “ten thousand.”

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Justification



To enhance the penalty for a corporate body which manufactures a medical device contrary to the Act from five thousand currency points to ten thousand currency points.

CLAUSE 58. IMPORTATION OF MEDICAL DEVICES

Clause 58 is amended—

(a) by substituting for sub clause (2) the following—

“(2) Notwithstanding subsection (1), the Authority may for a specified purpose, and subject to conditions the Authority may deem fit, authorise the importation of a medical device which is not licenced under this Act—

- (a) where the importation of the medical device is required by the Authority for purposes of registration, notification or listing of the medical device under this Act;
- (b) where the medical device is imported for purposes of conducting a clinical trial;
- (c) where the medical device is imported for personal use;
- (d) where the medical device is imported for an emergency situation;
- (e) where the medical device is imported for compassionate use;
- (f) where the medical device is imported under extra ordinary circumstances as prescribed in regulations made under this Act;
- (g) where the medical device is imported for approved scientific education and research.”

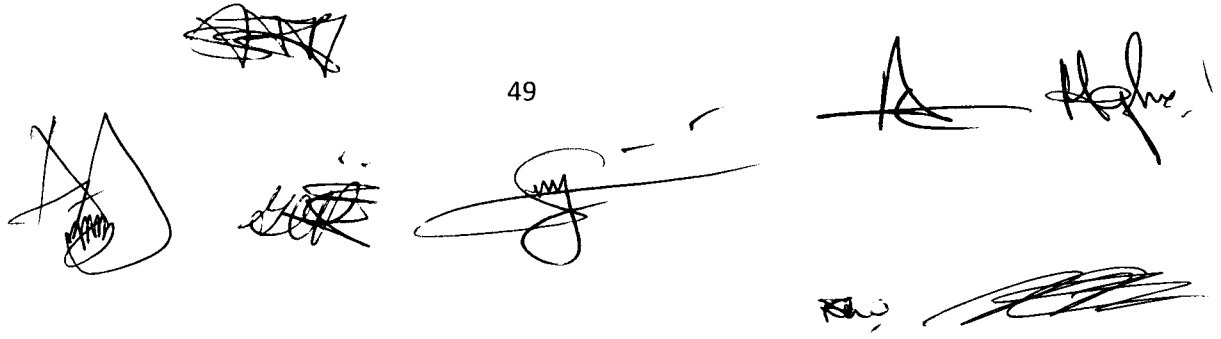
(b) in sub clause 6 (b)—


- (i) by substituting for the word “re-export”, the word “return”; and
- (ii) by substituting for the word “import”, the word “export”.

(c) in sub clause (8)(a) by substituting for the words “five thousand” the words “ten thousand”.

Justification

- To empower the Authority to make the decision for exemption of importation of a medical device without a licence.



- 
- To provide for the return of a medical device imported contrary to the provisions of this Act to the country of export.
 - To increase the penalty for a corporate body which imports a medical device contrary to this Act from five thousand currency points to ten thousand currency points.

CLAUSE 59. LICENCE FOR THE DISTRIBUTION OF MEDICAL DEVICES

Clause 59 is amended in sub clause (5)(a) by substituting for the words “five thousand”, the words “ten thousand”.

Justification


To enhance the penalty for distribution of a medical device without a licence by a body corporate from five thousand currency points to ten thousand currency points.

CLAUSE 60. LICENSING OF PREMISES TO BE USED FOR WHOLESALE OF MEDICAL DEVICES

Clause 60 is substituted for the following—

“60. Licensing of supply of medical devices by whole sale or retail and inspection of premises by the Authority.

- (1) A person shall not supply a medical device by wholesale or retail without a licence issued by the Authority.
- (2) A person who intends to supply a medical device by wholesale or retail shall, on payment of the prescribed fees, make an application to the Authority in the form prescribed by regulations made under this Act.
- (3) The requirements for carrying out of the business of wholesale or retail of a medical device, including the inspection of premises to be used for the carrying out of the business of wholesale or retail of a medical device, shall be prescribed by regulations made under this Act.
- (4) The Authority shall grant a person who satisfies the requirements under this section, a license to supply a medical device by wholesale or retail.



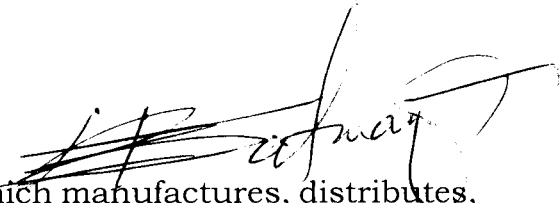
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- (5) A person issued with a licence to supply a medical device by wholesale or retail shall be required to comply with good storage and good distribution practices prescribed by regulations made under this Act.
- (6) The Authority shall before issuing a licence for the manufacture, importation, distribution, exportation or supply by wholesale or retail of a medical device, satisfy itself that the premises where the business is to be carried out are suitable for the business for which the licence is required.
- (7) For the purposes of subsection (6), a person who intends to apply for a licence for the manufacture, distribution, importation, exportation or dispensation of a medical device shall upon payment of the prescribed fees, make an application for a certificate of suitability of premises in respect of the premises at which the business activity is to be carried.
- (8) The Authority shall, prior to issuing a certificate of suitability of premises, inspect the premises, fixtures, equipment and other physical attributes of the premises to determine that the premises are suitable for the purpose for which the certificate is to be issued.
- (9) The requirement for issuance of certificate of suitability of premises shall be prescribed by regulations made under this Act.
- (10) A person who manufactures, distributes, imports, exports, or supplies by wholesale or retail a medical device contrary to this section commits an offence and is liable on conviction.
 - (a) in case of a corporate body, to a fine not exceeding ten thousand currency points; and
 - (b) in case of an individual, to a fine not exceeding five thousand currency points or imprisonment not exceeding five years, or both.”

Justification

- The amendments are for clarity in empowering the Authority to licence the business of wholesale or retail of medical devices.
- To empower the Authority to inspect premises for certification of suitability of premises before issuance of licence for manufacturing, distribution, importation, exportation or supply by whole sale or retail of medical devices.

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- 
- To enhance the penalty for a body corporate which manufactures, distributes, imports, exports or supply by whole sale or retail of medical devices without a licence from five thousand currency points to ten thousand currency points.

CLAUSE 61. REPORTING OF DEFECTS AND ADVERSE EVENTS TO AUTHORITY

Clause 61 is amended in sub clause (2) by substituting for the word “patient”, the word “person”.

Justification

- To widen the scope of applicability.

CLAUSE 62. EXPORTATION OF MEDICAL DEVICES

Clause 62 is amended in sub clause (5)(a) by substituting for the words “five thousand”, the words “ten thousand”.

Justification

The enhancement of the penalty for exportation of a medical device by a body corporate contrary to the provisions of the section is to deter potential offenders.

CLAUSE 64. REGISTRATION, NOTIFICATION AND LISTING OF COSMETIC PRODUCTS

Clause 64 is amended—

(a) by substituting for sub clause (2) the following—

“(2) Notwithstanding subsection (1), the Authority may for a specified purpose, and subject to conditions the Authority may deem fit, authorise the manufacture, distribution, importation, exportation or supply by wholesale or retail of a cosmetic product which is not registered, notified or listed by the Authority —

(a) where the cosmetic product is required by the Authority for purposes of registration, notification or listing of the cosmetic product under this Act;

(b) where the cosmetic product is required for purposes of conducting a clinical trial;

(c) with respect to importation where the cosmetic product is imported for personal use;

- (d) where the cosmetic product is required for compassionate use;
- (e) where the cosmetic product is required under extra ordinary circumstances as may be prescribed in regulations made under this Act; or
- (f) where the cosmetic product is required for approved scientific education and research.”

(b) in sub clause (6)—

- (i) in paragraph (a) by substituting for the words “five thousand”, the words “ten thousand”.
- (ii) in paragraph (b) by substituting for the words “five hundred”, the words “five thousand”.

Justification

- To empower the Authority to make the decision for exemption of the manufacture, distribution, importation, exportation or supply by wholesale or retail of a cosmetic product which is not registered, notified or listed by the Authority
- To provide for the return of a medical device imported contrary to the provisions of this Act to the country of export.
- To increase the penalty for a corporate body which imports a medical device contrary to this Act from five thousand currency points to ten thousand currency points.

CLAUSE 65. LICENCE FOR THE MANUFACTURE OF COSMETIC PRODUCTS

Clause 65 is amended in sub clause (6)(a) by substituting for the words “five thousand”, the words “ten thousand”.

CLAUSE 66. IMPORTATION OF COSMETIC PRODUCTS

Clause 66 is amended—

(a) in sub clause (2)—

- (i) by deleting paragraph (c); and

(ii) inserting immediately after paragraph (d), the following—

“(e)extra ordinary circumstances as may be prescribed in regulations made under this Act; or

(f)approved scientific education and research.”

(b) in sub clause 6(b), by—

- (i) substituting for the word “re-export”, the word “return”; and
- (ii) substituting for the word “import”, the word “export”.

(c) in sub clause (8)(a), by substituting for the words “five thousand”, the words “ten thousand”.

Justification

- For clarity
- To enhance the penalty for a corporate body which imports a cosmetic product contrary to the provisions of the Act.

CLAUSE 67. POWER OF MINISTER TO PROHIBIT IMPORTATION OF COSMETIC PRODUCTS.

Clause 67 is amended—

(a) by substituting for the phrase “on the advice of the Authority, by notice in three newspapers of national wide circulation”, the words “by statutory order”;

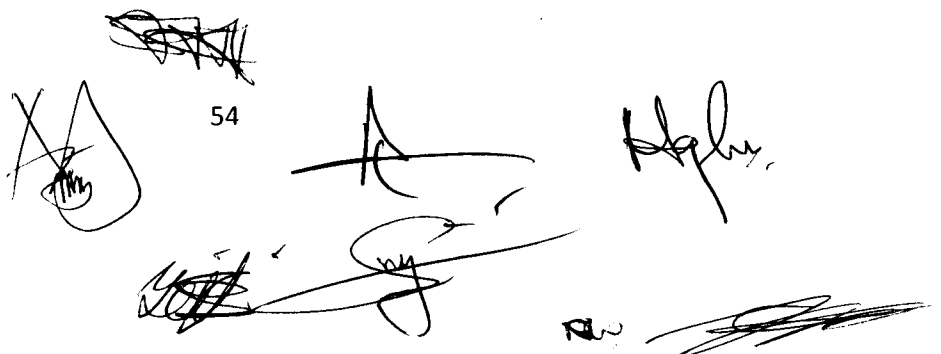
(b) in paragraph (a), by substituting for the word “risk”, the word “harm”;

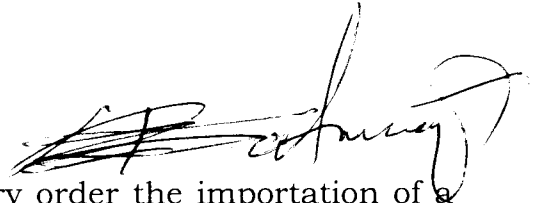
(c) by renumbering the clause as subclause (1).

(d) by inserting immediately after subclause (1), the following sub clause—

“The Minister shall, upon issuing the statutory order under subsection (1), publish in a newspaper of nationwide circulation a notice of the cosmetic product prohibited under that order.”

Justification

The bottom of the page contains several handwritten signatures and scribbles. A central number '54' is visible. The signatures are in various styles, some appearing to be initials or full names, and are scattered across the bottom half of the page.



To empower the Minister to prohibit by a statutory order the importation of a cosmetic product which may cause harm to human beings.

CLAUSE 68. LICENCE FOR DISTRIBUTION OF COSMETIC PRODUCTS

Clause 68 is amended in sub clause (5)(a) by substituting for the words “five thousand”, the words “ten thousand”.

Justification

To enhance the penalty for distribution of cosmetic products without a licence issued under this Act.

CLAUSE 69. LICENCE FOR EXPORTATION OF COSMETIC PRODUCTS

Clause 69 is amended in sub clause (5)(a) by substituting for the words “five thousand”, the words “ten thousand”.

Justification

To enhance the penalty for exportation of cosmetic products without a licence issued under this Act.

CLAUSE 70. CATEGORIES OF PUBLIC HEALTH PRODUCTS

Clause 70 is amended by inserting immediately after paragraph (d) the following—

“any other category as may be authorised by the Minister, with the approval of Cabinet.”

Justification

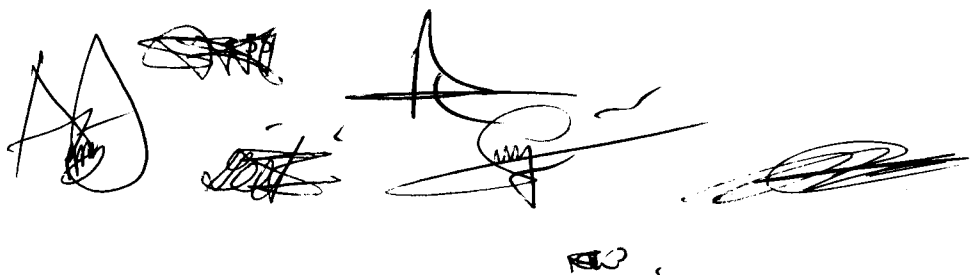
To provide for an avenue for emerging public health products that may require categorisation under this section.

CLAUSE 71. REGISTRATION, NOTIFICATION AND LISTING OF PUBLIC HEALTH PRODUCTS

Clause 71 is amended—

(a) by substituting for sub clause (2), the following—

“(2) Notwithstanding subsection (1), the Authority may for a specified purpose, and subject to conditions the Authority may deem fit, authorise the



manufacture, distribution, importation, exportation or supply by wholesale or retail a public health product which is not registered, notified or listed by the Authority —

- (a) where the public health product is required by the Authority for purposes of registration, notification or listing of the medical device under this Act;
- (b) where the public health product is required for purposes of conducting a clinical trial;
- (c) with respect to importation where the public health product is imported for personal use;
- (d) where the public health product is required for compassionate use;
- (e) where the public health product is required under extra ordinary circumstances as may be prescribed in regulations made under this Act;
or
- (f) where the public health product is required for approved scientific education and research.”

(c) in sub clause (6)—

- (i) in paragraph (a) by substituting for the words “five thousand”, the words “ten thousand”; and
- (ii) in paragraph(b) by substituting for the words “five hundred”, the words “five thousand”.

Justification

- To empower the Authority to authorize the manufacture, importation, exportation, importation or supply of public health products which are not registered, notified or listed under exceptional circumstances.
- To enhance the penalty for manufacture, importation, exportation, importation or supply of public health products which are not registered, notified or listed by the Authority.

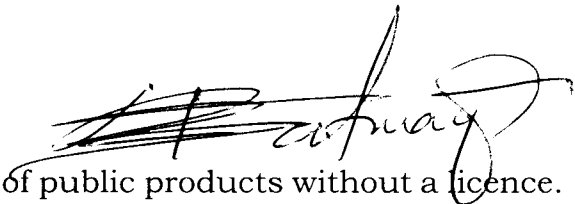
CLAUSE 72. LICENCE FOR MANUFACTURE OF PUBLIC HEALTH PRODUCT

Clause 72 is amended in sub clause (6)(a) by substituting for the words “five thousand”, the words “ten thousand”.

56

Justification

To enhance the penalty for the manufacture of public products without a licence.



CLAUSE 73. IMPORTATION OF PUBLIC HEALTH PRODUCTS.

Clause 73 is amended—

(a) by substituting for sub clause (2) the following—

“(2) Notwithstanding subsection (1), the Authority may for a specified purpose, and subject to conditions the Authority may deem fit, authorise the importation of a public health product which is not licenced under this Act where the importation—

- (a) is required by the Authority for purposes of registration, notification or listing of the medical device under this Act;
- (b) is required for purposes of conducting a clinical trial or field trial for the public health product;
- (c) is required for an emergency situation;
- (d) required for compassionate use;
- (e) is required under extra ordinary circumstances as may be prescribed in regulations made under this Act; or
- (f) is required for approved scientific education and research.”

(b) in sub clause 6(b) by—

- (i) substituting for the word “re-export”, the word “return”; and
- (ii) substituting for the word “import”, the word “export”.

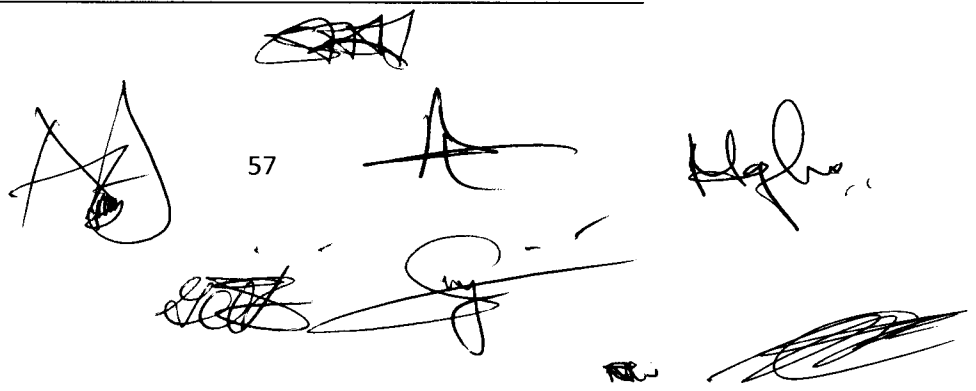
(c) in sub clause (8)(a), by substituting for the words “five thousand” the words “ten thousand”.

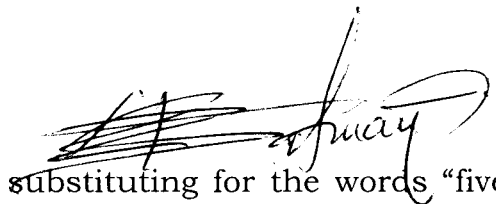
Justification

- It is a consequential amendment.
- To increase the penalty for a body corporate which imports a public health product contrary to this Act from five thousand currency points to ten thousand currency points.

CLAUSE 75. EXPORTATION OF PUBLIC HEALTH PRODUCTS

57





Clause 75 is amended in sub clause (5)(a) by substituting for the words “five thousand” the words “ten thousand”.

Justification

To enhance the penalty for exportation of public health products without a licence.

CLAUSE 77. REGISTRATION, NOTIFICATION AND LISTING OF NUTRITIONAL SUPPLEMENTS

Clause 77 is amended—

(a) by substituting for sub clause (2) the following—

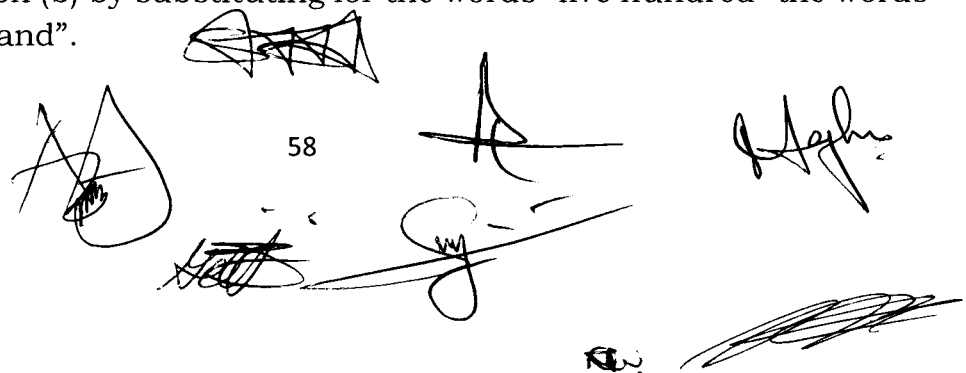
“(2) Notwithstanding subsection (1), the Authority may for a specified purpose, and subject to conditions the Authority may deem fit, authorise the manufacture, distribution, importation, exportation or supply by wholesale or retail of a nutritional supplement which is not registered, notified or listed by the Authority—

- (a) where the nutritional supplement is for purposes of registration, notification or listing of the nutritional supplement under this Act;
- (b) where the nutritional supplement is required by the Authority for purposes of registration, notification or listing of the nutritional supplement under this Act;
- (c) where the nutritional supplement is required for purposes of conducting a clinical trial;
- (d) with respect to importation where the nutritional supplement is imported for personal use;
- (e) where the nutritional supplement is required for compassionate use;
- (f) where the nutritional supplement is required under extra ordinary circumstances as may be prescribed in regulations made under this Act;
or
- (g) where the nutritional supplement is required for approved scientific education and research.”

(b) in sub clause (6) by—

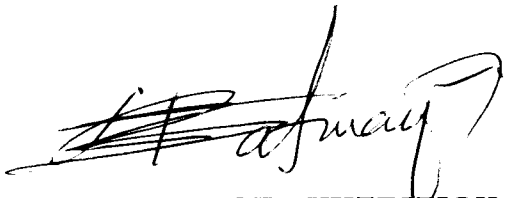
- i. in paragraph (a) by substituting for the words “five thousand” the words “ten thousand”; and
- ii. in paragraph (b) by substituting for the words “five hundred” the words “five thousand”.

58



Justification

- It is a consequential amendment.



CLAUSE 78. LICENCE FOR THE MANUFACTURE OF NUTRITIONAL SUPPLEMENTS

Clause 78 is amended in sub clause (6)(a) by substituting for the words “five thousand” the words “ten thousand”.

Justification

To enhance the penalty for a corporate body that manufactures a nutritional supplement without a licence.

CLAUSE 79. IMPORTATION OF NUTRITIONAL SUPPLEMENTS

Clause 79 is amended—

(a) in subclause (2) by inserting immediately after paragraph (d), the following—

- “(e)the importation is required for compassionate use;
- (f) the importation is required under extra ordinary circumstances as may be prescribed in regulations made under this Act; or
- (g)the importation is required for approved scientific academic research.”

(b) in sub clause 6(b) by—

- (i) substituting for the word “re-export”, the word “return”; and
- (ii) substituting for the word “import”, the word “export”.

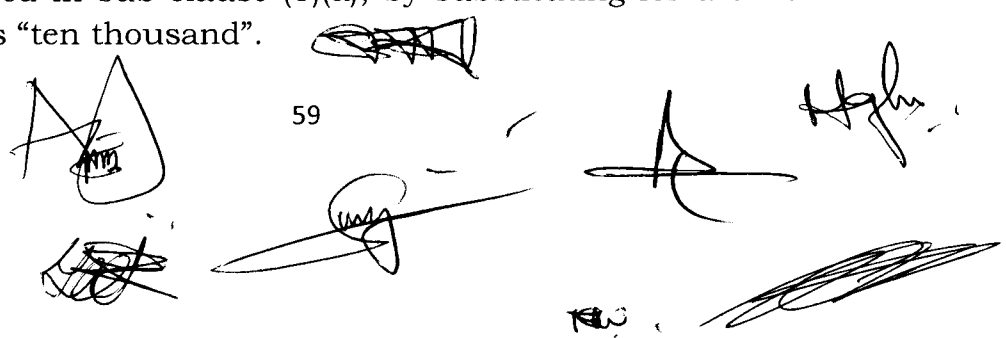
(c) in sub clause (8)(a) by substituting for the words “five thousand”, the words “ten thousand”.

Justification

- To enable the importation of a nutritional supplement for compassionate use, extraordinary circumstances and approved scientific and academic research.

CLAUSE 80. LICENCE FOR THE DISTRIBUTION OF NUTRITIONAL SUPPLEMENTS

Clause 80 is amended in sub clause (5)(a), by substituting for the words “five thousand” the words “ten thousand”.



Justification

- To enhance the penalty for the distribution of nutritional supplements without a licence issued under this Act.

CLAUSE 81. EXPORTATION OF NUTRITIONAL SUPPLEMENTS

Clause 81 is amended in sub clause (5)(a), by substituting for the words “five thousand” the words “ten thousand”.

Justification

- To enhance the penalty for exportation of nutritional supplements without a licence under the Act.

CLAUSE 83. STANDARDS FOR COSMETICS AND PUBLIC HEALTH PRODUCTS

Clause 83 is amended—

(a) by substituting for the headnote, the following—

“83. Conformity to standards of Authority

(b) by substituting for subclause (1), the following—

“(1) A person shall not manufacture, import, export, distribute or supply a regulated product which does not conform to the standards prescribed under this Act.”

(b) by inserting immediately after sub clause (1), the following—

“The Authority shall prescribe standards for regulated products under this Act.”

(c) in sub clause (3)(a) by substituting for the words “five thousand”, the words “ten thousand”.

Justification

- To avoid duplication of mandate between Uganda National Bureau of Standards and the Authority.
- To enhance the punishment for non-conformity to the prescribed standards.

CLAUSE 84. OBLIGATION FOR MANUFACTURER TO ESTABLISH MONITORING SYSTEM AND MONITORING OF REGULATED PRODUCTS

Clause 84 is amended—

(a) by substituting for the headnote, the following—
“Monitoring system and reporting of adverse reactions or adverse events of regulated products.”

(b) by inserting immediately after sub clause (3) the following—

“Where a manufacturer, distributor or importer of a regulated product becomes aware of any adverse reaction or adverse event arising from the use of a regulated product or which reveals any defect in the regulated product, the manufacturer, distributor, or importer, shall, in a form prescribed by regulations made under this Act, make a report to the Authority.”

(c) in sub clause (5)—

- (i) in paragraph (a) by substituting for the words “five thousand”, the words “ten thousand”; and
- (ii) in paragraph (b) by substituting for the words “five hundred”, the words “five thousand”.

Justification

- The insertion is to provide for compulsory reporting to the authority by manufacturers, distributors and importers, in case of an adverse reaction or adverse event.
- The amendment in sub clause (5)(a) and (b) is enhance the punishment for non-conformity to contravention of the provision.

CLAUSE 90. AUTHORISATION TO CONDUCT CLINICAL TRIAL OR FIELD TRIAL FOR REGULATED PRODUCT

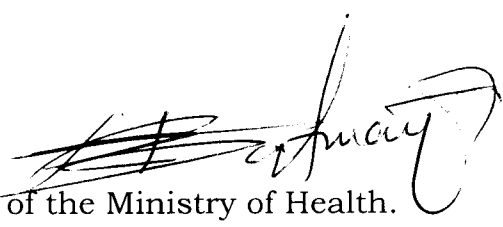
Clause 90 is amended by inserting immediately after sub clause (8), the following—

“(9) This section shall not apply to a clinical trial or field trial conducted by the Ministry in public interest.

(10) Notwithstanding subsection (9), the Ministry shall, while conducting a clinical trial or field trial, conduct the clinical trial or field trial in accordance with good clinical practices prescribed by regulations made under this Act.”

61

Justification



- To facility the seamless execution of the mandate of the Ministry of Health.

CLAUSE 95. DECEPTION OF CONSUMERS

Clause 95 is amended in sub clause (3)—

- (c) in paragraph (a), by substituting for the words “five thousand”, the words “one hundred and fifty thousand”; and
- (d) in paragraph (b), by substituting for the words “five thousand”, the words “twenty thousand”, and for the words “five years”, the words “fifteen years”.

Justification

- To enhance the punishment since deception of consumers directly affects the decisions of consumers and consumption of such products could lead to fatal results.

CLAUSE 96. ADVERTISEMENT OF REGULATED PRODUCTS

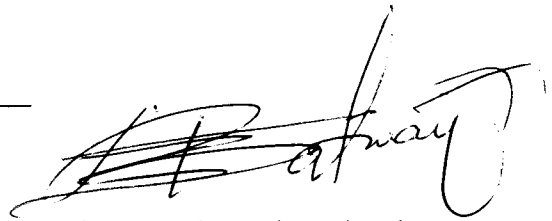
Clause 96 is amended by—

- (a) inserting immediately before sub clause (1), the following—
 - “(1) A person who intends to advertise a regulated product shall, upon payment of the prescribed fees and in the form prescribed by regulations made under this Act, submit the advertisement to the Authority for approval.
 - (2)A person who intends to advertise a regulated product by—
 - (a) publication of information on the regulated product or by promotion or distribution of information on the regulated product;
 - (b)bringing to the notice of the public, information on the regulated product by causing or permitting to be published, promoted or distributed, information on the regulated product;
 - (c) bringing to the notice of the public, information on the regulated product in any manner; or
 - (d) sponsorship or promotion of a regulated product,

shall comply with the requirements prescribed by regulations made under this Act.”



(b) substituting sub clause (1) with the following—
“(1) A person shall not advertise—



(a) a regulated product or cause any other product to be advertised as a regulated product; or

(b) a regulated product or cause a regulated product to be advertised in such a manner that represents the regulated product, as being usable for a purpose other than the purpose for which it was registered, notified or listed.”

(c) in sub clause (4)—

(i) in paragraph (a), by substituting for the words “five thousand”, the words “one hundred fifty thousand”; and

(ii) in paragraph (b), by substituting for the words “five hundred”, the words “twenty thousand, and the words “five years” the words “fifteen years”.

Justification

- To empower the Authority to approve all advertisements, promotions and sponsorship for regulated products for purposes of protecting the consumer.
- The redraft in sub clause (1) is for clarity.
- The amendment in sub clause (4) is to enhance the punishment since wrong advertisement of regulated products could mislead consumers to make uninformed decisions which could lead to fatal results.

CLAUSE 97. PROHIBITION OF FALSIFIED REGULATED PRODUCTS

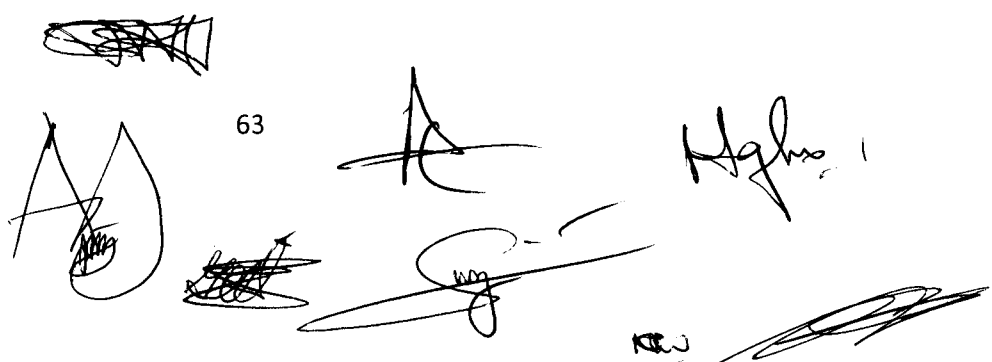
Clause 97 is amended in sub clause (3)—

(a) in paragraph (a), by substituting for the words “five thousand”, the words “one hundred fifty thousand”; and

(b) in paragraph (b) by substituting for the words “five thousand”, the words “twenty thousand”.

Justification

- The amendment in sub clause (3) is to enhance the punishment since falsifying regulated products are harmful to consumers and could lead to fatal results.



CLAUSE 98. PROHIBITION OF SUPPLY OF SUBSTANDARD REGULATED PRODUCTS

Clause 98 is amended—

(a) by deleting sub clause (3).

(b) in sub clause (4)—

(i) in paragraph (a), by substituting for the words “five thousand”, the words “one hundred fifty thousand”; and

(ii) in paragraph (b), by substituting for the words “three thousand”, the words “twenty thousand, and for the words “five years” the words “fifteen years”.

Justification

- The definition of the term “not fit for intended purpose” has been transferred to the interpretation section since it is used in other clauses outside clause 98.
- The amendment in sub clause (4) is to enhance the punishment since substandard regulated products are harmful to consumers and could lead to fatal results.

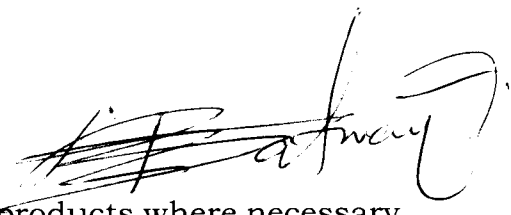
CLAUSE 99. ESTABLISHMENT OF THE NATIONAL DRUG AND HEALTH PRODUCTS LABARATORY

Clause 99 is amended by inserting immediately after sub clause (4), the following—

“For purposes of this section, analyst means a person who is qualified and designated by the Authority to perform laboratory examination, testing, and analysis of products regulated under this Act.”

CLAUSE 101. POWERS OF INSPECTORS

Clause 101 is amended in sub clause (1)(a) (i) by inserting immediately after the word “retain”, the words “or quarantine”



Justification

- To empower the inspector to quarantine regulated products where necessary.

CLAUSE 102. APPEAL TO THE HIGH COURT

Clause 102 is substituted for the following—

“Administrative review and appeal process

- (1) A person aggrieved by a decision or action of the Authority may, within thirty days after being notified of the decision, apply to the Authority for administrative review.
- (2) The Authority shall, after receipt of the application under subsection (1), determine the application within reasonable time.
- (3) A person aggrieved by the decision of the Authority made under subsection (2) may, within thirty days after being notified of the decision, appeal to the High Court.”

Justification

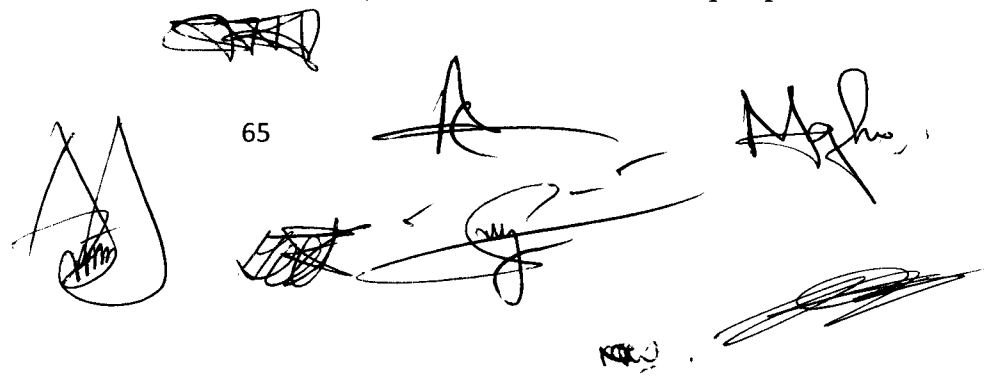
- To provide a clear and orderly mechanism for challenging enforcement decisions of the Authority, beginning with internal administrative review before recourse to court.
- This promotes procedural fairness by allowing the Authority an opportunity to reconsider its decision, and preserves the right of an aggrieved person to appeal to the High Court.

CLAUSE 103. DESTRUCTION OF PRODUCTS NOT FIT FOR INTENDED PURPOSE

Clause 103 is substituted for the following—

“103. Destruction of products under court order

- (1) Where a product regulated under this Act is, on testing and analysis by the Authority, found to be substandard, not fit for intended purpose or



falsified, the Authority shall apply to court for an order for the destruction of the product.

(2) Where the court is satisfied that the product is substandard, not fit for intended purpose or falsified, the court shall order the destruction of the product.

(3) Court may order the person granted the certificate of registration, notification or listing, or the authorised representative of that person, or the importer or manufacturer to—

(a) destroy the product regulated under this Act; and

(b) bear the cost of destruction.

(4) The Authority shall supervise the destruction ordered by court under subsection (3).

(5) The Authority shall, by regulations made under this Act, prescribe the manner in which a product regulated under this Act may be destroyed.”

Justification

- To empower the Authority to make the decision for determination of destruction of a product regulated under this Act, instead of the inspector.

CLAUSE 109. AUTHORITY TO ASCERTAIN THE QUALITY OF THE DRUGS OF THE NATIONAL MEDICAL STORES

Clause 109 is deleted.

Justification

- The clause is redundant because the Authority already has the general statutory mandate to regulate and assure the quality of drugs in Uganda, including in the public sector. Retaining a specific clause on National Medical Stores is unnecessary and may distort the distinction between the Authority’s regulatory role and the supply mandate of National Medical Stores.

CLAUSE 112. REGISTERS

Clause 112 is amended by substituting for sub clause (1), the following—

66

- (1) The Authority shall establish and maintain registers necessary for the performance of the functions of the Authority under this Act, including a register for—
- (a) registered, notified or listed drugs and regulated products;
 - (b) licensed manufacturers, distributors, suppliers, importers, exporters, wholesalers or retailers of drugs and regulated products;
 - (c) prohibited or banned drugs or regulated products or substances under this Act;
 - (d) authorised laboratories for carrying out functions of the Authority under this Act;
 - (e) lot release;
 - (f) clinical trials carried out under this Act;
 - (g) field trials carried out under this Act; and
 - (h) any other purpose as the Authority may deem fit.

Justification

- For clarity and to enlist all the registers required to be maintained by the Authority.

CLAUSE 113. POWER TO REQUIRE INFORMATION

Clause 113 is amended in sub clause (2) by substituting for the words “fifty hundred”, the words “five thousand”.

Justification

For clarity.

CLAUSE 118. REGULATIONS

Clause 118 is amended in sub clause (2)—

- (a) by inserting immediately before paragraph (a), the following—
“for registration, notification and listing of drugs including any conditions for registration, notification or listing of drugs;”
- (b) by substituting for paragraph (a), the following—
“for the registration, notification and listing of regulated products;”

(c) in paragraph (e), by substituting for the word “marketing”, the words “advertisement and promotion”

(c) by inserting immediately after paragraph (j), the following—

“(l) pharmacovigilance;

(j) classification of medical devices; or

(k) for suitability of premises for manufacture and distribution of products regulated under this Act.”

Justification

- To empower the Minister to make regulations for items prescribed under the substantive provisions but not included in the clause.

CLAUSE 120. REPEALS AND SAVINGS

Clause 120 is amended by deleting sub clause (3).

Justification

- Section 14 empowers NDA to be the licensing authority for export, import, production and distribution of Narcotic drugs for medical purposes and this has not been provided for under the Bill, so it is best to retain this mandate under the Narcotic Drugs and Psychotropic Substances (Control) Act, Cap. 37.

121. TRANSITIONAL PROVISIONS

Clause 121 is amended—

(a) by substituting for sub clause (1), the following—

“A member of the Board of the National Drug Authority in office at the commencement of this Act is eligible for appointment if he or she meets the terms and conditions for appointment prescribed under this Act.”

(b) by substituting for sub clause (2), the following—

“The Secretary to the National Drug Authority in office at the commencement of this Act shall continue in office until the expiry of his or her instrument of appointment and is, upon the expiry of his or her

instrument of appointment, eligible for appointment if he or she meets the terms and conditions for appointment prescribed under this Act.

(c) by substituting for sub clause (3), the following—

“At the commencement of this Act—

(a) all persons who were employed by the National Drug Authority shall continue in the employment of the Authority;

(b) the terms and conditions of service, including salary, on which a person referred to in paragraph (a) was employed, shall not be less favourable than the terms and conditions of service applied to the person before the commencement of this Act; and

(c) there shall be no break or interruption in the employment of the persons referred to in paragraph (a).

Justification

- The amendment provides a transitional safeguard of the employees of the Authority to ensure continuity in offering the services to the Authority following the commencement of the Act and prevents disruption in the functioning of the Authority.

CLAUSE 122. REGULATION OF VETERINARY DRUGS, VETERINARY MEDICAL DEVICES AND FIELD TRIALS

Clause 122 is amended in sub clause (2)—

(a) by substituting for paragraph (b), the following—

“any reference to clinical trials includes veterinary clinical trials and veterinary field trials”;

(b) in paragraph (c), by inserting immediately after the words “veterinary drugs”, the words “veterinary vaccines, veterinary biologicals, veterinary medicated feeds, veterinary hormones, veterinary herbal products or veterinary complementary medicine”;


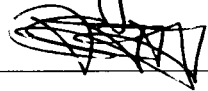
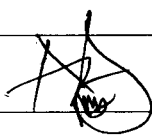
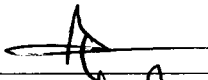
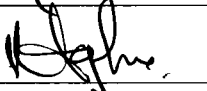
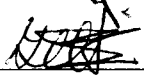

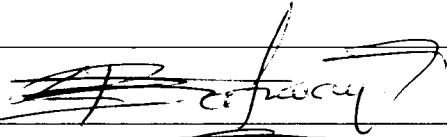

(c) by inserting immediately after paragraph (h), the following—

“any reference to pharmacovigilance includes ~~veterinary~~ pharmacovigilance;
any reference to drug advertisement and promotion includes promotion and advertisement of veterinary drugs, veterinary medical devices, veterinary vaccines, veterinary biologicals, veterinary medicated feeds and veterinary supplements, or veterinary medicated cosmetics;
any reference to cosmetics products includes veterinary medicated cosmetics;
any reference to herbal medicine and complementary medicine refers to veterinary herbal and veterinary complementary products; and
any reference to nutritional supplements includes veterinary supplements.”

Justification

- To qualify the provisions under the Bill to specifically apply to veterinary products.

**REPORT OF THE COMMITTEE ON HEALTH ON THE NATIONAL
DRUG AND HEALTH PRODUCTS AUTHORITY BILL, 2025**

No	Name	Constituency	Party	Signature
1	Hon. Dr. Ruyonga Joseph	Hoima West	NRM	
2	Hon. Dr. Opio Acuti Samuel	Kole North	Ind	
3	Hon. Bebona Babungi Josephine	Bundibugyo	NRM	
4	Hon. Laker Sharon Balmoyi	DWR-Gulu	NRM	
5	Hon. Isaac Otingiw	Padyere	NRM	
6	Hon. Nebanda Andiru Florence	DWR-Butaleja	NRM	
8	Hon. Kayagi Sarah Netalisire	DWR-Namisindwa	NRM	
9	Hon. Rutahigwa Elisa	Rukungiri	NRM	
10	Hon. Ayebare Margaret	DWR-Mbarara	NRM	
11	Hon. Dr. George Didi Bhoka	Obongi	NRM	
12	Hon. Chelain Betty Louke	DWR-Amudat	NRM	
13	Hon. Sekyanzi Benard Kirya	Budyebo	NRM	
14	Hon. Dr. Ninkusiima John Paul	Ibanda South	NRM	
15	Hon. Nandagire Christine Ndiwalana	Bukomansimbi North	NUP	
16	Hon. Dr. Kagabo Twaha Mzee	Bukoto South	NUP	
17	Hon. Dr. Kamara Nicholas Thadeus	Kabale Municipality	FDC	
18	Hon. Dr. Batuwa Timothy	Jinja West	FDC	
19	Hon. Dr. Lulume Bayiga Micheal	Buikwe South	DP	

No	Name	Constituency	Party	Signature
20	Hon. Auma Kenny	DWR Kwania	UPC	
21	Hon. Zawedde Victorious	DWR Nakasongola	Ind	
22	Hon. Mukhaye Miriam	DWR Mbale	Ind	
23	Hon. Nantaba Idah Erios	DWR Kayunga	Ind	
24	Hon. Col. Dr. Nekesa Victoria	UPDF		
25	Hon. Kamateneti Joselyine	DWR Ntungamo	NRM	