PHARMACEUTICAL SOCIETY OF UGANDA

(PSU)

POSITION ON THE PROPOSED MERGER OF ALL HEALTH PROFESSIONAL COUNCILS INTO ONE REGULATORY COUNCIL. BY AN OMNIBUS UGANDA HEALTH PROFESSIONAL REGULATORY COUNCIL (UHPRC) BILL 2023

NOVEMBER 2023

Executive Summary

The Pharmaceutical Society of Uganda (PSU) is a body corporate that is established under the pharmacy and drug Act Cap 280 with the council of the Pharmaceutical Society of Uganda as the governing body charged under section 21 with the general responsibility for securing the highest practicable standards in the practice of pharmacy and with the administration and management of the society. The Pharmaceutical Society of Uganda is a self-sustaining professional regulatory body corporate and doesnot draw any money from the treasury.

The Council of the Pharmaceutical Society of Uganda notes with concern the attempt to merge the existing professional regulatory Councils into one regulatory Council called the Uganda Health professionals regulatory Council as proposed in the Uganda Health professionals regulatory Council bill 2023. The bill among other things seeks to regulate, supervise, control, register and license all health professionals under one umbrella including those that have been best and most efficiently regulated like the pharmacy profession under their Professional body; the Pharmaceutical Society of Uganda.

The decision is premised on the huge cost of administration to the treasury and duplication of roles and functions among the councils which is not true. The merger if done is likely to affect greatly public health and safety as a result of the likely inefficiency and poor regulation which comes along with blurring regulation of the professions into one entity.

As per the statement on Rationalization of government Agencies by the Hon Minister ofpublic service dated 11th August 2021, Annex I, S/NO. 13 (Health), The Pharmaceutical Society of Uganda (PSU) was and/or is not among the listed agencies or authorities which were/are listed for merger and its members as key stakeholders have never been consulted on the matter.

Furthermore, the Council's concerns are also premised on the fact that Omnibus regulation of all health professionals by one Council raises several public health and safety concerns some of which are highlighted here below;

1. Lack of Specialization: Different health professions have unique skill sets and expertise, hence a single council will not adequately address these specialized needs of each profession, potentially leading to a lack of focus on specific issues and decreased research out-put which is detrimental to public health and safety.
2. Uniform standards: Setting uniform standards for all health care professionals may not account for the diversity in practice areas and may and/or likely to deter growth for those diverse practice areas hindering innovation, research out and flexibility in healthcare delivery.

3. Resource Allocation: Different health professions require varying resources, training and regulations, which an Omnibus approach will allocate resources inefficiently or disproportionately to certain professions, potentially jeopardizing public safety.

4. Stake holder Representation: Health Professionals and communities they serve have different needs and perspectives; a single council may struggle to represent the interests of all stakeholders adequately.

5. Delays and Bureaucracy: A centralized council will introduce bureaucratic inefficiencies, slowing down the process of setting standards, issuing licenses, or responding to emergencies in respective professional practice.

6. Ethical Conflicts: Inter-professional conflicts will arise when a single council oversees multiple professions potentially compromising ethical standards, decisions-making and a huge public health threat in a spree of ethical dilemmas which would greatly affect performance and health care delivery in the country resulting into a catastrophe.

7. Emerging New health Professions: Professions are emerging into new specialized health professions. In prudence, the regulatory function should be growing into new specialized regulatory entities rather than bedeviling the already existing and self-sustaining agencies into a treasury dependent and straining council.

Globally, the available literature on pharmacy regulation is skewed towards self-regulation/independent Regulation which favors vertical linear integration for purposes of proper collaboration and coordination with similar professional bodies like the federation of international pharmacists and the Common Wealth Pharmacists Association.

Accordingly, The Pharmaceutical Society of Uganda rejects the proposed bill because of the above public health concerns, deviation from global best professional regulation practices in addition to inadequate and/or no consultations of key stakeholders of which pharmacists are among and limited/failure to do proper regulatory impact assessment (RIA). We argue that Pharmacy is a unique profession in its nature as it is a multidisciplinary specialized profession whose scope is not only limited to human health, but also to Veterinary Pharmacy, Cosmetology Pharmacy, Radio-Pharmacy for both human, veterinary and Industrial use, Precision Medicine, Pharmacognosy, Medicines Supply Chain Management among others.

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Background

General Observations

The Pharmaceutical Society of Uganda (PSU) is a body corporate that is established under the pharmacy and drug Act Cap 280 with the council of the Pharmaceutical Society of Uganda as the governing body charged under section 21 with the general responsibility for securing the highest practicable standards in the practice of pharmacy and with the administration and management of the society. The Pharmaceutical Society of Uganda is a self-sustaining professional regulatory body corporate and doesnot draw any money from the treasury.

Whereas Government came up with Policy for Rationalisation of Government Agencies and Public Expenditure (RAPEX) which was adopted by the cabinet on 22nd February2021 under minute no.43 (CT 2021) took a decision to merge, mainstream, and rationalize Government Agencies, Commissions, and Authorities, to optimize public expenditure for efficient and effective service delivery. The exercise commenced in 2021 for a period of two years (2021/22 and 2022/23) and the Ministry of Public Service was directed to implement changes,

And whereas the East African Community common market protocol provides for the signing of mutual recognition agreements between member states to enable trade in professional services,

As per the statement on Rationalization of government Agencies by the Hon Minister ofpublic service dated 11th August 2021, Annex I, S/NO. 13 (Health), The Pharmaceutical Society of Uganda (PSU) was and/or is not among the listed agencies or authorities which were/are listed for merger and its members as key stakeholders have never been consulted on the matter.

It is important to note that Section 2.1.2(e) of the Revised Background Paper – 7th Ordinary Meeting of the EAC Sectoral Council on Regional Cooperation on Health- EAC Headquarters – Arusha, Tanzania – 26th to 30th March 2012 (Page 6), provides for setting up a national health regulatory authority in each EAC partner State having a clearly defined relationship with the various existing separate National Health Professional Boards and Councils in each Country.

In light of the above EAC policy proposals

1. At regional level the East Africa Medical and Dental Practitioners Council, and the Allied Health Professionals Council of East Africa have already been established with efforts to establish the East Africa Pharmaceutical Council already under way.

2. The previous EAC Regional integrations have taken an approach of establishing harmonized independent sub-sector EAC agencies like the Inter-University Council of East. Africa, East Africa health Research Commission, East Africa Science and Technology Commission, EAC Medicines Regulatory Harmonization Program, e.t.c BUT NOT a sector wide harmonization framework like the Uganda Health Professional Regulatory Council Bill (UHPRC) proposes. The importance ofthis approach is to ensure sub-sector details are captured in integration efforts and not blurred into sector wide policy formulation.

3. The Pharmaceutical Society of Uganda strongly supports the proposal that professional integration at regional level takes the shape of the intra-professional/vertical approach and the establishment of the East Africa Professional Regulatory Authority be between respective East Africa Regional Independent Professional bodies.

4. The pharmaceutical society of Uganda further opines that the proposed East Africa Health Professions Authority (EACHPRA), concentrates on regional policy, and coordination issues and inter-profession council issues, BUT save the regulatory, operational and management matters to the various legally existing National Health Profession Councils and Boards.

5. However, though not recommended, if the Uganda National Health Professions Authority MUST be formed, it should play the role of provision of oversight, coordination and guidance but not regulatory in line with minute 2.4 of the 3rd meeting of the EAC National Pharmacy Boards/Councils held 27th to 28th February 2012 in Arusha, Tanzania at Kibo Palace Hotel (Ref: EAC/TF/222/2012).

6. Pharmacy in particular is a unique profession that requires special regulatory attention and support. Unlike other health professions which focus on human health, Pharmacy profession is not only concerned with human health but also animal health, through manufacture and custodianship of medicines for both human and veterinary use, provision of first treatments to both human and veterinary patients, manufacture and handling of radio-pharmaceuticals for both health and industrial applications, cosmetic pharmacy, pharmacognosy, precision medicine, pharmaceutical analysis etc thus it doesn't fit in the regulatory framework proposed by UHPRC bill 2023.

7. Globally, the available literature on pharmacy regulation is skewed towards self-regulation which favors vertical linear integration for purposes proper collaboration and coordination with similar professional bodies like the federation of international pharmacists, the Common Wealth Pharmacists Association among others as summarized in tables 1 (a) & 1(b):

A Global view of pharmacy profession regulation trends country by countryacross the world

Table 1 (a) Countries with independent/self-regulating pharmacy councils

S.N	COUNTRY	PHARMACY REGULATORY BODY	RESPONSIBLE LEGISLATION
	CANADA	National Association of Pharmacy regulatory authorities (NAPRA) An alliance of provincial and territorial Pharmacy Regulatory Authorities (PRAs) across Canada. All states have established autonomous PRAs responsible for regulation of pharmacy profession and practice such as; the Alberta College of Pharmacy, College of Pharmacists of Manitoba, Newfoundland and Labrador Pharmacy Board, and Ordre des pharmaciens du Québec	Provincial and territorial legislation like 1. Health Professions Act Chapter h7 of 2023, Alberta 2. The Pharmaceutical Act (C.C.S.M. C. P60) Regulation 185/2013, Manitoba 3. PHARMACY ACT, 2012 4. Loi sur la pharmacie (Pharmacy Act), 2022
	BRITAIN	General Pharmaceutical Council (GPC) established by the Pharmacy Order 2010 as an independent statutory regulator	The Health Act 1999 as amended by the Health and Social Care Act2008 Medicines Act 1968 Poisons Act 1972

	AUSTRALIA	Australian Pharmacy Council This council, initially called the Council of Pharmacy Registering Authorities (COPRA) was formed to harmonize the different state Pharmacy regulatory authorities (PRAs) in relation with regulatory requirements and facilitate communication among pharmacy registering authorities The PRAs include 1.Pharmacy Board of the Australian Capital Territory 2.Pharmacy Board of New South Wales 3.Pharmacy Board of the Northern Territory 4.Pharmacists Board of Queensland 5.Pharmacy Board of South Australia 6.Pharmacy Board of Tasmania 7.Pharmacy Board of Victoria 8.Pharmaceutical Council of Western Australia	1. Health Professionals Act 2004 2. Pharmacy Act 1964, Pharmacy Practice Act 2006 (to commence on a date to be specified) 3. Health Practitioners Act 2004 4. Pharmacists Registration Act 2001 5. Pharmacists Act 1991, 6. Pharmacy Practice Act 2007 (to commence in 2007 or 2008) 7. Pharmacists Registration Act 2001 Health Professions Registration Act 2005 8.(commenced on 1 July 2007) 9.Pharmacy Act 1964, Pharmacists Bill 2006

	SOUTH AFRICA	South African Pharmacy Council (SAPC) Established by the Pharmacy Act, No. 53of 1974 and amended 2002 It provides for the establishment of the South African Pharmacy Council and forits objects and general powers; extends the controlof the council to the public sector; and provides for pharmacy education and training, requirements for registration, the practice of pharmacy, the ownership of pharmacies and the investigative and disciplinary powers of the council; and provides for matters connected therewith.	PHARMACY ACT NO. 53 OF 1974 Last amended by veterinary and Para-Veterinary Professions Amendment Act, No. 10 of 2002
	NIGERIA	Pharmacy Council of Nigeria (PCN) PCN is a Federal Government parastatal established by the Pharmacy Council of Nigeria Act 2022, charged with the responsibility of regulating and controlling pharmacy education, training and practice in all aspects and ramifications, including regulating Pharmacy Technicians and Patent and Proprietary Medicines Vendors (PPMVs)	Pharmacy Council of Nigeria (Establishment) Act, 2022
	GHANA	PHARMACY COUNCIL, GHANA The Pharmacy Council is a statutory body established by an Act of Parliament, the Health Professions Regulatory Bodies Act (Act 857) to regulate the practice of Pharmacy in Ghana. The same act establishes other independent Councils to regulate other health professions 1. Allied Health Professions Council 2. Nursing Midwifery Council 3. Psycholoy Council	Health Professions Regulatory Bodies Act, 2013 Act 857 PHARMACY ACT - 1994(ACT 489)

	KENYA	Pharmacy and Poisons Board Established by An Act of Parliament to make better provision for the control of the profession of pharmacy and the trade in drugs and poisons	PHARMACY AND POISONS ACT CHAPTER 244 Revised Edition 2012[1989]
	TANZANIA	PHARMACY COUNCIL Established by the pharmacy act, 2011 to regulate and control pharmacy professional, practice and business in Tanzania	The pharmacy act, 2011
	RWANDA	The Rwanda National Pharmacy Council (NPC) It is an independent statutory authority accountable for the regulation of the pharmacy profession in Rwanda. It was set up by law No 45/2012 of 14/01/2013. The NPC is responsible for ensuring that the rules, honor, and dignity of the pharmacy profession are complied with and ensure the protectionof public health.	LAW No45/2012 OF 14/01/2013 ON ORGANISATION, FUNCTIONING AND COMPETENCE OF THE COUNCIL OF PHARMACISTS

Table 1 (b) nations with merged regulatory councils

S.N	COUNTRY	PHARMACY REGULATORY BODY	RESPONSIBLE LEGISLATION
	ZAMBIA	THE HEALTH PROFESSIONS COUNCIL OF ZAMBIA Established by an act to continue the existence of the Medical Council of Zambia and rename it as the Health Professions Council of Zambia; provide for the registration of health practitioners and regulate their professional conduct; provide for the licensing of health facilities and the accreditation of health care services provided by health facilities; provide for the recognition and approval of training programs for health practitioners; repealthe Medical and Allied Professions Act, 1977; and provide for matters connected with or incidental to the foregoing	THE HEALTH PROFESSIONS ACT, 2009

KEY

OTHER CONTINENTS	AFRICA	EAST AFRICA

It is observed from the data that most countries world over, pharmacy profession is regulated independently of other health professions because of the uniqueness of the profession as its practice combines both human and veterinary medicine in all its fields.This is considered the best practice for regulation of the professions.

Specific Observations

The Report of the Ad-hoc committee of the 11th parliament on the February 2021 Cabinet Decision to rationalize government agencies, did not include the Pharmaceutical Society of Uganda among the agencies to be rationalized in the Ministry of health which decision we want to believe was based on proper

analysis that pharmacy is unique as it cuts across human and veterinary medicine. This report arose from a final report of Ministry of Public Service (2017) on a comprehensive review and restructuring of Government ministries, departments and agencies that did not as well include the Pharmaceutical Society of Uganda.

In July 2016, a USAID Consultant report highlighted several areas of weakness of different health professional laws and recommended several improvements.

The report indicated the need to strengthen the existing individual health professional council laws. The report also recommended the review and amendment of the Medical and Dental Practitioners Act, Nurses and Midwives Act and the Allied health professionals Act. It further recommended for extensive consultation of health professional councils during the process. This report as well did not include the Pharmacy and drugs Act 1970, Cap 280 and Pharmaceutical Society of Uganda, its regulatory arm and our assumption is that pharmacy regulation in Uganda was the benchmark which informed such recommendations.

In the same spirit, the 2019-2021 research conducted by Makerere universityschool of public health (Uganda) in collaboration with Warwick Business school (UK), Strathmore business school (Kenya), KeMRI Wellcome Trust (Kenya) and university of Oxford (UK), titled "policy brief on strengthening health professional regulation in Kenya and Uganda." recommends with evidence for developing systemic regulation across health professions and healthcare organizations and decentralized regulatory monitoring, engagement and supervision.

According to the Republic of Uganda Evidence Based Policy Making – A Guide to Regulatory impact assessment (RIA) page 6 provides that RIA should be done to assist governments in designing modern, precise, targeted regulation that achieves legitimate policy aims with the minimum burden on those affected by addressing five broad principles that underpin good policy:

1. Accountability - to cabinet and parliament, to users and the public.
2. Proportionality - regulations should be proportionate to the risk.
3. Consistency – laws should be predictable, so that people and businesses know where they stand.
4. Transparency - regulation should be open, simple and user-friendly
5. Targeted – regulation should focus on the problem with minimum side effects.

The rationale and criteria used by the drafters of the UHPRC Bill 2023 with limited or no consultation at all of all stakeholders in the rationalization exercise in respect to Pharmaceutical Society of Uganda whether or not it should be included in the said Bill was a potential over-sight disaster, an assumption that the bill will reduce Cost on the treasury was a falsy and also that the believe there is duplication of roles is merely simplistic in nature. It should be noted that, in regards to PSU the reason above are not correct as justified bellow;

1. PSU doesn't draw any monies from the treasury and in its current self-sustaining state and highly validated regulatory structure and Capacity does not need a merger as it's modal of regulation reduces the financial burden on the treasury and if the merger is done it will have deer catastrophic consequences on public and animal health and safety listed in the executive summary supra and also add more burden on the treasury rather than reducing it.

2. PSU governance and fully fledged administrative structures are unique and specialized to their function of regulating pharmacy practice and do not duplicate any other role of other agencies as claimed in the UHPR bill 2023. Pharmacy practice is a very specialized branch of medicine with specialized practice of handling and manufacture of medicines of both human and veterinary health, nuclear pharmacy, pharmacognosy, precision medicine etc, which areas require independent and specialized regulation in conformance with international standards thus it doesn't fit in the regulatory framework proposed by the UHPRC bill 2023.

3. There were very limited consultations if any or no consultations at all conducted by the ministry of public services involving the key stakeholders and the wider public to collect the stakeholders' views before the bill was drafted which in itself sets a bad legislative precedent in this country as pre-legislative consultations area cornerstone in making any good law.

Our observation indicates a rationalisation exercise that was embarked on with a limited comparative study in the region. From the 58 paged report of the Ad- hoc Committee of the February 2021 Cabinet Decision to Rationalize Government Agencies (Dated 28th Feb 2022), it is evident that Kenya, Ethiopia, Zimbabwe, Tanzania did what Uganda is doing to bureaucratize regulatory agencies but as a result, they lost heavily on the production quantities and quality of professional and are currently in the process of reversing their decisions they had earlier taken.

Public Health Consideration

Rationalization of health professional bodies, if not reviewed, may greatly affect Uganda's public health by destroying the safe guarding efforts and roles which are currently being played by the independent professional councils and initiate the public into a spree of public health threats.

The incidence, prevalence, mortality, morbidity, quality of life, and economic costs of diseases that are affected by the quality and safety of health care services provided by different health professionals must be well evaluated using appropriate disease modelling techniques to inform the comparison in regards tocost of regulation versus the cost on the public health outcome.

Agent-based modelling (ABM)

Agent-based modelling (ABM), a computational modelling technique as a RIA could have been used to simulate and analyze how the merger might affect healthcare outcomes and patient safety by modelling the behaviors and interactions of various stakeholders, including healthcare professionals, regulatory authorities, and patients. Here's how ABM could be applied:

1. Agent Representation:

Healthcare Professionals: Agents in the model could represent different healthcare professionals, such as medical and dental practitioners, nurses, pharmacists, and allied health practitioners. Each agent would have attributes representing their specialization, experience, adherence to professional standards, and other relevant characteristics to inform the decision.

Regulatory Authorities: Regulatory bodies, whether separate or consolidated, would be represented as agents. These agents would have attributes related to their capacity for oversight, enforcement, and response to complaints or violations.

Patients: Patients could be represented as agents with attributes reflecting their health status, healthcare needs, preferences, and experiences.

2. Environment:

The model's environment would simulate the healthcare system in question, including hospitals, clinics, pharmacies, and other healthcare facilities. The model would also incorporate factors like healthcare resources, infrastructure, and technology.

3. Interactions:

Agents interact with each other and the environment. For example, healthcare professionals interact with patients by providing care and making treatment decisions. Regulatory authorities interact with professionals by conducting inspections, issuing licenses, and responding to complaints.

4. Rule-Based Behaviour:

Each agent follows a set of rules and behaviours based on its attributes. For instance, healthcare professionals adhere to their professional standards, and regulatory authorities enforce these standards.

5. Scenarios and Experiments:

We can define different scenarios within the model, such as the current state of separate regulatory bodies and a scenario where they are consolidated. Experiments can be conducted to observe how the system responds to these changes.

6. Data Inputs:

The model can be informed by real-world data and statistics, such as historical healthcare incidents, regulatory compliance records, patient outcomes, and costdata. This data is used to parameterize the model and make it more realistic.

7. Simulation and Analysis:

The ABM simulates the interactions of agents over time, allowing us to observe emergent behaviours and patterns. We can track various metrics, such as medication errors, patient wait times, professional misconduct, and patient safety incidents.

8. Comparison and Evaluation:

The model can be used to compare the outcomes of different scenarios, such asthe impact of consolidating regulatory bodies on patient safety and healthcare quality compared to the status quo. We can quantify changes in healthcare outcomes, costs, and safety incidents.

9. Policy Evaluation:

ABM allows for the evaluation of different policy options. We can test variations of the consolidation scenario and assess the potential risks and benefits of eachoption.

10. Feedback and Iteration:

Based on the results of simulations, policymakers and stakeholders can make informed decisions. If the model suggests negative outcomes from consolidation, adjustments to the proposed changes can be made and tested in the model.

The Pharmaceutical Society of Uganda remains available to support governmentin regards to this possible evaluation and give its expert opinion and the long term experience in professional regulation.

Clause by clause Review of the Uganda Health Professionals Regulatory Bill 2023.

Page of the bill	Clause/ sub-clause/ paragraph	Observation on the selected clause	Recommendation	Justification
Page 1, 2 & 11	Defects in existing law, Remedies proposed.	Part 1 : Preliminary- "An act to consolidate the law on the regulation, supervision and control of the health professionals; establishes the Uganda Health regulatory Council to regulate all health professionals. It also repeals the Medical and Dental Cap 272, the Pharmacy and Drugs Act 280, (PDA) the Nurses and Midwives Act Cap 274 and the Allied Health Professionals Act 268."	1. The idea of rationalizing PSU should be dropped, and the Pharmacy and drug Act 1970, Cap 280 be removed from the laws intended to repealed by the UHPRC Bill 2023' - The regulation of the pharmacy profession be maintained as it is under the PDA 1971 Cap 280. 2. Remove all provisions relating to the repeal of the PDA Cap 280 3. Recommend for amendment of the PDA and other health professionals	1. There is no reference in all the prior public documents on government position to rationalize agencies to include Pharmaceutical Society of Uganda which is legally established under Section 5 of the Pharmacy and Drugs Act, Cap 280. 2. The PSU was erroneously included in this Bill. 3. PSU does not draw funds from the treasury 4. PSU was never consulted before drafting of this bill

			council Acts to strengthen their functions andself-sustainability.	

Page 1	Clause 2	1. That there is Duplication of roles by existing structures of Health Professional Councils 2. That there is huge Cost on the treasury by health Professional regulatory Councils including PSU	PSU and the whole Pharmacy practice regulation should be removed from the Bill, its regulation be maintained as it is under the PDA 1971 Cap 280.	1. PSU doesn't draw any monies from the treasury and is a self-sustaining institution. 2. PSU structure doesn't duplicate roles of any other agency, it is a specialized structure for regulation of one profession of pharmacy that is very unique and different from all other health professions, practice include Veterinary Pharmacy, Medicine manufacturing, Clinical Pharmacy, Medicines Supply Chain, Pharmacognosy, Radio-pharmacy etc 3. The Cost of Administration of Professional councils is far below the cost of the Public health threat that willarise from scaling down regulatory capacity of the health professionals councilin one omnibus and un specialized health professionals regulatorycouncil.

Page 1.	Clause 2 & 3	Establishment of UHPRC and its functions as a remedy to the stated defects.	1. The UHPRC Bill 2023 be struck out and amendments to improve regulatory capacities and self-sustenanceof the existing different health professional regulatory Acts be prioritized 2. The PSU may be benchmarked on our success story of self-sustainability and high standard of professional regulation as it has always been.	1. The defect it is remedying a non-existing problem of a huge cost on treasury in respect to Pharmaceutical Society of Uganda 2. The UHPRC will create a very complex ungovernable and inefficient professional regulatory structure. 3. The remedy defeats the international principles of a professional self-regulationto manage behaviour, standards, and ethics of members of the same profession.

Pg 3-9		Arrangement of Sections	The bill be struck out as vague and rashly drafted for unclear and ulterior motives	The sections of the proposed UHRPC Bill is on average 99% a duplication of all the acts of the individual health professional councils', It only focuses on merging of Councils into one Council but it doesn't take into consideration of the implicationsof the blurring of individual professional regulation capacities and the likely catastrophic public health threats that will arise.
Pg 12	Part 1 Clause 1	Interpretation The bill interpretation clause is narrow in scope and eventhe few terms defined are lacking in light of the international accepted definitions of such terms e.g - drug -health unit	1. The Bill be struck out and any future drafting should be done in consultation with the relevant expert professional bodies. 2. The bill should not involve PSU Council that is charged with regulating professionals handling drugs for all human and veterinary health, this involves relationships with very many professionals outside the human health.	The interpretations in the bill are inconsistent and limited in scope with the known standard generic definitions. All terms related to Pharmacy practice where not defined. For example; "drug" the definition of the drug is inappropriate. Drug is not only limited to human health but also animal/veterinary health. Drug can be a poison or medicine. Pharmacists are experts in drugs and cannot be merged with non-drug experts.

Pg 13,	Part II, Clause 3	1.Registration and Licensing of professionals or health units	a. Delete this clause . b. The Pharmacy Professional regulation must not be merged with other professional regulation agencies to avoid professional isolation in the region and the world . 2. The inter- professional integration of like professions should be encouraged e.g the East Africa Pharmacy Council, East Africa Medical and Dental Practitioners Council etc	1. Registration of different professions have unique and generally agreed international standards which can't be done by one omnibus institution In particular the PSU conducts Several Qualifying exams at international standard, supports under graduate and post-graduate training of registered pharmacists, and Continuous professional development. 2. The PSU is a member of international Organizations with other Pharmacy Societies like the International Pharmaceutical Federation (IPF), Common Wealth Association of Pharmaceutical Societies that recognize only qualifications of member Pharmacy Institutions.The Omnibus Council will isolate Pharmacists trained in Uganda and failure of their recognition globally.

Clause 3, b,c,e,f	These clauses provide for overall upholding of the highest standard of professional practice.	a Delete these clauses 2. Merging a well-developed and efficiently regulated profession of pharmacy with other professions waters down the efforts and strides achieved over the years of the establishment of the Council, into a new start-up regulatory policy. This is very detrimental to Public health.	1. PSU since its establishment has successfully implemented upholding the highest level of professional practices in the Country at over 98% efficiency, mergingit will definitely pose a big public health threat, 2. All pharmacists practicing in the Country are dully licensed by PSU. Their records are well maintainedin a digital single-click database and their practice is monitored online and updated regularly and country wide support supervision done on every pharmacist practice setting.

	Clause 3,d	The Clause provides for support accreditation of Education Standards with Higher Education Regulatory institutions (HERI),	Delete the clause. This bill is not needed in its form as it will affect catastrophically the quality of professional training in Higher Education Institutions.	-This is a misguided function, HERI like the National Council forHigher Education engage professional bodies during accreditation of programs of study for their particular professional expertise to guide onthe curriculum and minimum teaching standards, IN the Omnibus arrangement of the UHPRC, this function will blur dueto lack of focus by the entity on one profession education attributes,

Pg 14,	Clause 4	Composition of the Council	1. This Bill is unnecessary and a threat to public health and should be struck out. 2. The Bill is very detrimental to professional growth and development for most professions and will create a lot of inter-professional conflicts.	Membership of the Council is misguided and very unfair populating membership with majority members of one professional cadre-ship(Medical and Dental Practitioners) and bundling other professions in subgroups, this is erroneous andis made in bad faith, with the intention of creating of professional dominance of some professions while sabotaging the growth of other professions. E.g 1. Allied Health is a Group of very many professional cadres represented by one person 2. Midwives and Nurses are two different professions represented by one person. 3. Pharmacy represented by one person only However Medical Practice has over three membership slots for DGHS, Medical and Dental Members and the likely appointment of chairperson being one of them.
	clauses 4,6,7,8, 9	Th excessive Power of the Minister respect to Appointments and removal from office of members of Council of the authority	The Bill was hurriedly drafted and should be struck out for insufficiency in substance of reason and law.	The Power of the Minister is excessive in respect to Appointments and removal from office of members of Council of the authority Such excessive power is liable to abuse and may put healthy professional regulation under big threat, consequently posing a crisis for public health.

Pg 16,	Clause 8	1. According to the Bill the Chief Registrar appointment by Health Service Commission yet responsible to the Council is a supervisory error. 2. According to the Bill the Chief registrar Mandatorily is supposed to be a registered Practitioner.	1. This Bill should be struck out to defend the public from catastrophic health threats arising from professional unethical conflicts and ulterior motives. 2. This Bill is not coming to Parliament in Good Faith but a clandestine scheme to sabotage other noble professions.	1. The Council not appointing its secretary and accounting officer, it is very likely to promote insubordination of the officer to the Council at the detriment of the professional regulation mandate, causing a very big risk to public health. 2. This is another example of Professional sabotage and promotion of a bad faith bill where Medical Practitioners wish to control and curtail other independent professions. This is very un-ethical and falls short of all international standards. (According to the Bill's Definitionof a practitioner it means a medical or dental practitioner)

Part VI, Pg 74,	Clauses 127-143 Pharmacy Practice and Establish ment of the Pharmace utical Society of Uganda	-All the clauses in this Part are a duplication of the PDA Cap 280, they are a mere copy and paste of the PDA. -Whatever the bill is proposing is already provided for in the PDA, copying and pasting it is very irrational and ambiguous.	Delete all the provisions of Part VI, Clauses 127-143 of the Bill	-the PSU is already established byan Act of Parliament (PDA Cap 280) -PSU is a self-sustaining agency with no cost to Treasury -the Bill adds a cost burden to government by establishing a new PSU as a government costing Centre. -the bill poses a threat to public health if professional councils are merged from already validated and well-developed councils to an amorphous structure of very many other professions. -the bill is a waste of time to parliament as it provides for already existing laws. Parliament will be burdened to read clause by clause of already approved law. This is a waste of tax payers money.
Part VII, Pg 83	Clauses 144, 145	The bill Repeals all the existing health laws regulating the professional practice and at the same time re-establishes another council elected by PSU at its AGM and without functions.	The UHPRC Bill 2023, be struck out as unnecessary and a danger to public health. In any case all provisions relating to Pharmacy practice Must be deleted.	1. Repealing the PDA Cap 280 that has effectively regulated the Practice of Pharmacy, as a self-sustaining institution of PSUis a catastrophic mistake that has dire public health consequences.

	Schedule2 and 3 Seal and Procedureof meetings of Council and Meeting of the Society	1. The UHPRC Bill 2023, Establishes the Council under Clause 2. 2. The schedules are also a copy and paste of the PDA Cap 280, The bill defines the Council as though the Bill was an extension of the PDA 3. The Council remains as it is in the Bill, with its composition and the manner in which it is elected for PDA but without any function. 4. Schedule 3, Paragraph 1(1) provides for a Council that is elected by the same Council Annually The UHPRC Bill therefore creates two Councils causing confusion.	The schedules 2 and 3 be deleted from the Bill	The Bill creates multiple councils with no clearly defined relationship and roles. PSU was smuggled into the bill. It was not among agencies to be merged.

	Schedule2 and 3 Multiple common seals for PSU and the UHPRC	1. The UHPRC Bill, creates several seals, one for the UHPRC under Clause 2 (3 and 6), and the other under part VI clause.129(3) for the PSU as a common seal for body corporate	Delete all schedules underpart VI clause .129(3) in the Bill.	This is already provided for in the PDA Cap 280. The PSU has a common seal as a body corporate. PSU was smuggled into the bill. It was not among agencies to be merged.

Conclusions

1. There was inadequate pre-legislative consultations if any or completely no pre-legislative consultations, thus no regulatory impact assessment was done before drafting of the bill which is setting a bad legislative process precedent.
2. The UHPRC BILL 2023 is a total departure from the provisions of East African community (EAC) Sectoral Council on Regional Cooperation on Health-EAC Headquarters – Arusha, Tanzania – 26th to 30th March 2012 (Page 6), which provided for setting up a national health regulatory authority in each EAC partner State having a clearly defined relationship with the various exist ng separate National Health Professional Boards and Councils in each Country as opposed to merging them.
3. The bill introduces a professional regulatory model which contradicts the global best benchmarked professional regulatory practices of independent regulation. The position on best professional regulatory practices is what Kenya is following. The Health Professional Councils cannot be mechanically merged due to their different mandates and unique practice areas.
4. The bill establishes the UHPR
policy formulation and supervision of health workers/professionals which are core functions of the health ministry.

5. The bill acknowledges the strength and elaborative structures in the existing health professional councils under the current laws and neither identifies nor address any defect in the existing health professional councils (HP), instead it duplicates the very laws it faults and does not address the emerging global technological trends in professional practice e.g Clinical pharmacy, Industry pharmacy, Pharmacognosy, precision medicine, health informatics, radio/Nuclearpharmacy among others.

Recommendations

We make the following recommendations that;

1. The bill be rejected in its totality as unnecessary and removed from the records of Parliament of Uganda should it be presented there in its current form.
2. The relevant laws establishing Health Professional Councils (HP) should be strengthened through amendments rather than repealing them. In particular, the Pharmacy and Drugs Act CAP 280 should be amended to address any prevailing gaps and strengthen regulation of the pharmacy profession and pharmacy practice in tandem with best international practices.
3. T(EAC) Sectoral Council on Regional Cooperation on Health of maintaining the existing HP, the July 2016 USAID consultant recommendations, and a policy brief research by Makerere University and others on strengthening profession regulation in Kenya and Uganda (Supra), should be followed as a guide to legislation of HPCs
4. Pharmacy profession remains independently regulated in line with the global best practices as elaborated in our observations above.
5. Members of pharmaceutical Society of Uganda should be consulted before any further steps are taken on laws which affect the pharmaceutical sector as experts in pharmacy and pharmaceuticals.
6. That the uniqueness of pharmacy profession should be considered in future on matters or proposed laws like the UHPRC bill as pharmacy cuts across both human medicine and veterinary medicine practice.

Per medicatum servium

(With medicines we serve)

Dr Lutoti Stephen

Secretary, Pharmaceutical Society of Uganda