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THE REPUBLIC OF UGANDA

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IN ANY CORRESPONDENCE ON MH/02/H
THE SUBJECT PLEASE QUOTE no

17th July, 2018.

The Rt. Hon. Speaker,
Parliament of Uganda
KAMPALA.

Rt. Hon. Speaker,

**RE: ISSUES OF CONCERN RAISED BY THE PLENARY ON THE
UGANDA NATIONAL HEALTH LABORATORY SERVICES
BILL 2016**

This is to acknowledge receipt of the letter by the Rt. Hon. Deputy Speaker to me dated 30th April 2018, referenced DSP/18 concerning the delay to present the UNHLS Bill 2016 to the plenary.

I am pleased to report that my Ministry has prepared responses to the issues raised by the Committee on Health and the Plenary as directed by the Rt. Hon. Deputy Speaker.

Hon. Speaker, I request for an appointment to give you a brief at your earliest convenience before you schedule me to present our responses to the Plenary.

Attached is a copy of the responses for your perusal.

Dr. Aceng Jane Ruth
MINISTER

- Cc: Rt. Hon. Deputy Speaker of Parliament
- Cc: Rt. Hon. Prime Minister
- Cc: The Chairperson - Committee on Health
- Cc: Hon. Minister of State for Health (General Duties)
- Cc: Hon. Minister of State for Health (PHC)
- Cc: Permanent Secretary, Ministry of Health
- Cc: The Clerk to Parliament
- Cc: Ag. Director General Health Services

18 JUL 2018

Handwritten notes:
The Genl
Please place
the bill
the Admin p/w
1/8/18

Handwritten notes:
PS
Please make
comment
17/7/18

RESPONSES BY THE HON. MINISTER OF HEALTH TO ISSUES RAISED BY MEMBERS OF PARLIAMENT ON THE UNHLS BILL 2016.

Rt. Hon. Speaker,

My Ministry presented the Uganda National Health Laboratory Services (UNHLS) Bill 2016 for debate on the floor of Parliament on 7th February 2018. A number of issues were raised by the honorable members to which I would like to respond as follows: -

It should be noted that over 70% of medical (curative) and public health (preventive) decisions on disease management and control depend on quality laboratory results. Many common diseases in Uganda including communicable diseases such as Malaria, TB, HIV/AIDS, Typhoid; Viral Hemorrhagic Fevers like Ebola, Marburg, Crimean Congo Hemorrhagic Fever; Zoonotic diseases like Brucellosis, Anthrax; and Non-Communicable diseases like Diabetes, Liver cirrhosis, kidney disease, Sickle Cell and High Cholesterol disease cannot be conclusively diagnosed without laboratory testing.

It has been globally acknowledged that organized, well-coordinated National Health Laboratory Systems are a cornerstone for the attainment of the Sustainable Development Goals (SDGs), particularly goal three (3) that is concerned with good health and wellbeing for all societies. Health laboratory services are also key to the successful implementation of the International Health Regulations-2005 (IHR2005), and the Global Health Security Agenda (GHSA), so the World Health organization has recommended that all countries strengthen their laboratory services by, among other things, establishing strong identifiable institutions to provide stewardship and governance for sustainable quality laboratory services.

The health laboratory subsector in Uganda has massively grown over the years, from a single laboratory in the then whites-only Hospital in Nakasero in 1926 (current Nakasero Blood Bank), to over 3500 laboratories, today.

Rt.Hon. Speaker, Laboratories are good only when they produce accurate and reliable results; but they can be extremely misleading and dangerous when the results provided are not true. Misdiagnosis often leads to improper medication, wastage of resources and death due to inappropriate treatment and continued risk of spread of disease to the population. This can only be avoided when there is a well-coordinated and managed National Health Laboratory system.

Unfortunately for a very long time, the country has faced critical challenges of poor quality of health laboratory services on a number of occasions where a patient obtains different results from different laboratories for the same tests done on the same day. We have to stop this, and therefore the urgent need for a technically competent institution such as UNHLS that will provide services of standardized testing procedures, ensure accreditation of Laboratories to International Standards and continuously monitor the quality of testing services to ensure that laboratory results issued to the public are correct and reproducible.

In the Health sector we work with multiple partners who offer and/or support laboratory services, and the activities of these numerous partners need to be properly coordinated, guided and checked.

Rt. Hon. Speaker, I would like to thank all the Hon. Members who contributed to the debate on the Uganda National Health Laboratory Services Bill on 7th February 2018. I critically checked in the Hansard and found that a total of 32 members contributed to the debate, 16 of whom out rightly supported the Bill, 9 did not support, 3 were neutral and 4 either gave information or asked questions. But even then, the majority of those who did not support indicated that they would support the Bill if only my ministry provided clarifications on issues they raised. I now have the honor to respond to the issues as follows: -

1. Status of the National Health Laboratory Policy and Strategic Plan

Rt. Hon. Speaker, the Ministry of Health formulated the first National Health Laboratory Services Policy in the year 2009, and a 5 year strategic plan in 2010 whose implementation ended in 2015. The Health Laboratory Policy has just been revised and a second five year strategic plan for the period 2015 to 2020 is being implemented. Copies of these documents are available for honorable members' reference.

2. Honorable members asked why we should establish an authority. They argued that we may want to create an authority for purpose of creating jobs for some people at the expense of the health budget.

Rt. Hon. Speaker, Laboratory services are very critical for health care service delivery and yet technically very complex in requirements such as human resources, equipment, reagents, performance procedures and processes. Uganda's population has grown to over 36 million people.

The national economy is steadily growing, more people are having more disposable income and many Ugandans are living longer. There is therefore increase in diseases of lifestyle and old age. Outbreaks of emerging and re-emerging diseases are on the increase as well. Consequently, there is an expanding demand for quality and responsive laboratory services to diagnose and monitor, with precision, both communicable and non-communicable diseases.

The country needs to take advantage of the current global technological advancements, national and international partnerships that drive genuine investments in the health laboratory sub-sector, to address these needs. Establishment of the UNHLS will create a framework that will efficiently extend quality laboratory services to all Ugandans through;

- a) Improved resource mobilization for laboratory infrastructure improvement.
- b) Setting and monitoring standards for public and private health laboratories.
- c) Monitoring adherence to delivery of quality laboratory services throughout the national health laboratory network.
- d) Monitoring laboratories and ensuring proper control while handling, transporting, or storing samples and materials containing highly infectious disease-causing organisms such as Ebola, Marburg, Polio, Hepatitis B, and Cholera to avoid intentional or unintentional spillage to the environment and the community.
- e) CPHL/UNHLS has a biorepository that has stored samples and infectious materials for purpose of research since 1990s. The law will enable use of the materials in research for new drugs and vaccines.
- f) Enable government to stop researchers from shipping samples for analysis outside the country when we have capacity, to avoid exporting Ugandan jobs.
- g) Generation of income from samples requiring complex testing brought from outside the country for analysis in CPHL and NTRL, which is currently done for free.

The UNHLS will continue to function within the available vote under the Ministry of health as indicated in the certificate of financial implications. However, the institution will be able to mobilize additional funding from other sources. It is clear therefore, Rt. Hon. Speaker, that this endeavor is not about creating jobs for some people at the expense of the health budget. But rather creation of a critical technically competent institution with mandate to streamline the delivery of reliable health laboratory services for all Ugandans and people in the region, using the available

resources and with capacity to mobilize more resources through partnerships and new innovations.

3- Honorable members asked; how has business been handled before?

Rt.Hon. Speaker, the Central Public Health Laboratory (CPHL) and the National Tuberculosis Reference Laboratory (NTRL) function as national reference laboratories for both the public and private sectors. In that capacity, they carry out specialized testing for complex diseases (Sickle Cell, HIV Viral Load, Hepatitis B, Early Infant HIV Diagnosis, TB Drug Resistance Testing, and Food testing for contamination) and disease outbreak confirmation. Both laboratories have been internationally accredited to provide technical support to more than 20 reference laboratories on the African continent under the auspices of World Health Organization's Regional Office for Africa (WHO-AFRO). The laboratories have received several International awards from the African Society for Laboratory Medicine, and World Health Organization for their outstanding performances compared to other global players. It is only in Uganda where the two laboratories have not yet been recognized!

The Central Public Health Laboratory (CPHL) was administratively assigned additional role of stewardship of the national health laboratory services network in the country by the Ministry of Health. So, the institution carries out the following additional functions:

- Initiation of policies and setting of standards and technical guidelines for the national health laboratory network and assessing health laboratories within the country for national certification.
- Accreditation of laboratories to ensure that services meet standards.
- Coordination of health laboratory equipment, reagents and supplies, in-service training, biosafety/biosecurity, health laboratory information management systems and health laboratory quality assurance for the more than 3000 laboratories in the network.
- Setting up and supervising a national system of transporting samples from lower health facilities to reference laboratories for high-tech testing.

We are now seeking legal mandate to enable this institution to perform these critical functions and more.

4- Honorable members wanted to know the functions of the established UNHLS

Rt. Hon. Speaker, pages 6 and 7 of the Bill state the functions of UNHLS to be established as:-

- To coordinate activities of laboratories that are vested in UNHLS and act as overall authority on health laboratory services in Uganda
- To initiate, guide and coordinate the development of national health laboratory policies, guidelines and strategic plans
- To set standards for; health laboratory service delivery, service providers and lab facility infrastructure at the various levels of the national health delivery system
- To monitor the quality of health laboratory services by using the national health laboratory standards
- To support laboratories to obtain International Accreditation
- To coordinate capacity building/training, proficiency testing and national health laboratory improvement programs
- To offer reference and specialized reference services within the health laboratory sub-sector
- To analyze laboratory data and provide information on a regular basis for policy formulation, planning and decision-making
- To provide diagnostic testing and laboratory-based surveillance of diseases of epidemic potential and public health importance
- To coordinate laboratory components in national disaster preparedness and response
- To undertake operational research to support improvement in health service delivery system in the country
- To perform any other function in relation to strengthening laboratory service delivery system in Uganda.

5- Honorable members wanted to know statistical data on actual number and categories of laboratories in the country by; type, location and level of service

Rt. Hon. Speaker, there are **1,908** legally Gazetted laboratories in the country as shown by level of health facility, catchment area served and category (public, faith based, private).

Level of Health Facility	Catchment area	Total number (Public & Faith-based)	Total number (Private)
National Specialized Reference labs	National	6	-
National Referral Hospital Labs	National	2	-
Regional Referral Hospital labs	Health region	16	-
General Hospital labs	One or more districts	139	15

Health Centre IV labs	County /Constituency	196	15
Health Centre III labs	Sub-County	1283	242
Grand Total	1,908	1,636	272

Rt.Hon. Speaker, the country has only 1908 legally registered and recognized health laboratories in the public, faith based institutions and private sector. Please note that private sector laboratories reported here are only 272, serving private hospitals/ health centers and other stand-alone laboratories. An additional estimated total of about 2000 private health laboratories operate in small clinics and pharmacies. It is through enactment of the UNHLS bill that a mandate can be given to UNHLS to regulate and accredit these private laboratories to ensure that they are not only registered but also meet acceptable standards of service delivery to the people of Uganda.

6- Honorable members wanted to know the types of equipment and reagents used in the laboratories

Rt. Hon. Speaker, The Ministry has a Standard Test Menu, harmonized testing Techniques and a List of Supplies and equipment for the different tiers of Health Laboratories in Uganda.

I would like to mention however, that some of these equipment are currently not functioning; either because of lack of supplies, or due to break down. The cause of this is thought to be lack of the appropriately skilled personnel to operate and maintain the equipment, as we are not able to attract and retain skilled personnel due to our current inadequate Human Resource structure. This is one of the reasons we need UNHLS to take full responsibility for resource mobilization, personnel training and service standardization.

7- Honorable members wanted to know the status and performance of laboratories country wide before the UNHLS bill is enacted

As mentioned earlier, the country has 1,908 legally registered laboratories. There is a tiered national health laboratory network to serve various levels of health service delivery; beginning with Health Centers III up to National Referral Hospitals as well as National Specialized Reference Laboratories.

Rt.Hon. Speaker, Laboratory service is one of the most expensive components of healthcare system. When the Ministry formulated the Laboratory policy in 2009, most of these laboratories were in a sorry state and we realized that we could not afford to have all of them functioning optimally.

We therefore chose 100 laboratories (called hubs) strategically distributed throughout the country, and improved them in terms of infrastructure, equipment, reagents and supplies, human resource, and quality management system so that they are able to **function optimally** to offer specialized reference testing such as CD4, Liver and Kidney function tests, complete blood counts, and some of them do culture and sensitivity.

A transport system was then established to transfer samples from levels where they could not be tested to the hubs where testing can be done and results returned to the facility using motorcycles.

Considering that the existing Human Resource Structure was not able to support the national testing needs, the Ministry attracted more than 500 additional staff with support from Partners to work in some of these hubs, including over 100 in CPHL itself carrying out testing for HIV Viral Load for the whole country, disease outbreak investigations and sickle cell screening among others.

In order to ensure quality laboratory services, MOH/CPHL established a national quality laboratory management system, adopted from the WHO standards which is strengthening the hubs for International Accreditation. **Three of the hubs (Kayunga, Kiryandongo and Nsambya Hospitals) just got accredited to ISO Standards last May.**

Rt. Hon. Speaker, this means our hub laboratories are providing laboratory services of the highest quality possible, which can be trusted throughout the world. So we need this law in order to sustain these achievements and hasten the pace of having all the laboratories in the country accredited.

8- Honorable members were concerned about funding of UHNLS, which is largely supported by donors currently. “Won’t such support at one time dwindle and thus create pressure on government?” they asked

Rt.Hon. Speaker, the current achievements of the National Health Laboratory Service delivery system would have been impossible without additional funding from our Partners. Needless to say, all our Partners are supportive of the UNHLS Bill, and there is no doubt that they will continue supporting the institution until it is able to stand on its own.

It has already been indicated in the certificate of financial implication that there will be no need for additional funding when the Bill is passed into law.

Enactment of the UNHLS bill will only increase institutional capacity to mobilize funding through partnerships and collaborative undertakings including research with local and International Partners for sustainability. The Law will also provide an opportunity for the National Health Laboratory Services to tap into the un-explored specialized private laboratory services at the local market, the East African Community (EAC), the African region and the world at large.

It should be remembered Rt. Hon. Speaker, that we refer our people to undergo laboratory tests in South Africa and India on a massive scale every day, but this law will help us to establish capacity to do these tests locally in Uganda hence saving Government the expenses while generating income for sustainability of the institution.

9- Honorable members were concerned as to why we could not have one comprehensive bill that takes care of all kinds of laboratories – forensic, animals, plants, water and environment, and laboratories in secondary schools and Universities, among others

Rt. Hon. Speaker, these are quite different specialty areas which require different human resource skills, and the tests done are different.

The only interest we have in testing samples from animals, food or water, is when investigating a particular disease incidence that has affected health of human beings, and we do have a mechanism for intersectorial collaboration under the ‘**one health**’ platform.

As for forensic analysis, we had mentioned it in the bill because there are cases where laboratory results from our health facilities have been used as evidence in the courts of law. But later on, during consultative process by the health committee we found that in forensic medicine, laboratory tests are done primarily for crime investigation which is a domain of Internal Affairs as opposed to our case where tests are done with primary objective of disease diagnosis. We then agreed to drop forensic analysis from the objects of the bill. But we shall still share the resources we have in case we are required and when it’s appropriate to provide services or information to the Ministry of Internal Affairs, Uganda Police Force or the Courts of Law.

10- Rt. Hon. Speaker, I am aware of the concerns raised by H.E. the President on the many authorities and/or government agencies, some of which have duplicate roles and therefore need merger, to which the Hon. Members referred.

In his letter, which was also reiterated by the **Rt. Hon. Prime Minister**, the President guided that Government will only create new agencies where it is considered very critical, and with strong justification, and that there must be no role duplication by a government department or should be a money generating agency. The UNHLS Bill is very critical to the proper functioning and quality of health laboratory services in Uganda. Once passed into law, all functions related to health laboratory services will be performed by UNHLS within the Ministry of Health, and so there will be no role duplication. Most importantly Hon. Speaker, the law is expected to enable the institution to mobilize its additional resources from donations, grants, technical consultancies, research/partnerships and by providing services to the private sector and countries within the region, as stated earlier. Moreover the benefits that will accrue to the nation as a result of UNHLS regulating laboratory services and controlling standards to enable provision of quality laboratory services is immeasurable financially.

11- Honorable members wanted to know the personnel in-charge of laboratory operations in Uganda, and their levels of qualification and specialty.

As for the laboratory staffing **Rt. Hon. Speaker**, Uganda has a pool of laboratory professionals trained at various levels including Certificate, Diploma, Bachelors, Masters and PhD degrees. These include a mixture of scientists who go directly to study laboratory medicine while others first qualify as Medical Doctors before specializing in Laboratory medicine (Pathology) at Master's degree level. The country therefore has a number of highly qualified professionals who are able to effectively provide the skills required in the health laboratory subsector.

Bachelor's degree training was started in the country 20 years ago, and yet we cannot employ the graduates because the current staffing structure allows employment of Certificate and Diploma holders only. Currently some of the additional staff we employ are supported by our Partners. Mildmay Uganda, which is mentioned in the Hansard is one such Partner. We need this law to create a structure that will facilitate attraction and retention of these highly skilled people into our health laboratory system to take care of the current scientific and technological complexities. It should be noted however, that they will be absorbed on Government terms.

12. Honorable members were concerned about the positions of the Executive Director and Deputy Executive Director in terms of reporting channels. They also wanted to know the fate of NTRL staff following passing of the Bill

Rt. Hon. Speaker, these issues are very critical. In the UNHLS bill, whereas appointment of the Executive Director is made by the Minister on recommendation from the Board, appointment of the Deputy Executive Director will be made by the Board, and he/she shall perform roles delegated by the Executive Director whom he/she reports to.

As for the staff of NTRL, they will be treated the same way as CPHL staff and so they will automatically become staff of UNHLS.

In conclusion the Rt. Hon. Speaker, I want to reiterate that laboratory services are critical in the health service delivery system, contributing the bulk of diagnostic services and promoting evidence-based medical practice. Improving the quality of laboratory services reduces the cost of healthcare significantly as medicines are given to patients only when Doctors are absolutely sure of their necessity. Some members may be tempted to think that we would rather put all the resources into laboratory reagents and equipment instead of using the resources to establish an institution to manage the laboratory services. I wish to assure members that without proper technical leadership, those resources will not be utilized appropriately. In any case the institution will help in mobilizing more resources for laboratory services in the country.

It is therefore my prayer Rt. Hon. Speaker, that UNHLS Bill is passed into law to enable the Ministry of Health manage laboratory services effectively, both in the public and the private sectors, for the betterment of the people of Uganda.

FOR GOD AND MY COUNTRY.

Hon. Dr. Jane Ruth Aceng
MINISTER OF HEALTH