THE REPUBLIC OF UGANDA

MINISTRY OF HEALTH

STATEMENT TO PARLIAMENT ON THE STATUS OF THE NATIONAL FOOD AND DRUG AUTHORITY (FDA) BILL.

Dr. Aceng Jane Ruth

Minister for Health
4th February, 2020

Rt. Hon. Speaker of Parliament,

Hon. Members of Parliament,

On 6th January 2020, I received the following questions for oral answer raised by Hon. Mbwatekamwa Gaffa. The question raised was that;

Under the present legal framework, the National Drug Authority is mandated to regulate drugs in the Country while the Uganda Bureau of Standards regulates food safety and quality. This has created poor coordination in administration of food and drug safety given the correlation between the two.

Aware that that there is urgent need government to streamline the food control system by transforming the National Drug Authority into a modern and effective National Food and Drug Authority:

i. When will the Minister present a Food and Drug Bill to Parliament for First reading
ii. Is the Minister aware of the inordinate delay in presenting this Bill and the consequences on the lives of Ugandans?
iii. Would the Minister consider allowing the Member asking the question to introduce a Private Member's Bill is after one month Government has still not presented it to Parliament for First Reading?

Rt. Hon. Speaker and Hon. Members,

The NFDA Bill, which has undergone extensive stakeholder consultation, is now ready to be presented to Cabinet and subsequently it will be laid on the table in Parliament.

Rt. Hon. Speaker and Hon. Members,

I am well aware of the delay in presenting this Bill. The principle aim of this Bill is to address the gaps related to regulation and control of the safety and quality of food, medical & veterinary devices, cosmetics and chemicals for public health use. Until this Bill is enacted into Law, the regulatory gaps will continue to pose risks to food safety, public health, the environment, as well as having serious consequences to trade in these products.

Rt. Hon. Speaker and Hon. Members,

The inordinate delay to presenting this Bill to parliament has been occasioned by prolonged delay in achieving consensus by some stakeholders on some of the provisions of the Bill which I have highlighted below;

The process of developing the Bill started in 2009 when the Ministry of Health (MOH) consulted all key stakeholder ministries on the draft memorandum for transformation of National Drug Authority (NDA) into National Food and Drug Authority (NFDA). However, during presentation of the Cabinet Memorandum to Cabinet in September 2009, Ministry of Agriculture, Animal Industry & Fisheries (MAAIF) objected to MOH as the Lead Ministry for Food Safety in Uganda.

Cabinet then directed the National Planning Authority (NPA) to coordinate all stakeholders involved and come up with a way forward. NPA carried out a research and benchmarking and presented its final report to Cabinet with recommendations in 2012. It was until then that the MOH presented the revised Cabinet Memo (CT: 2012/113), basing on recommendations in the NPA Report, to Cabinet and obtained Cabinet approval and instructions to draft the NFDA Bill. This alone caused delay to the Bill drafting process for about three (3) years.

Between 2012 and 2017; progress was made in drafting of the Bill which was informed by several stakeholder consultations. A final draft of the Bill was developed in September 2017 and was ready for presentation to Cabinet.

In November, 2017, Ministry of Agriculture, Animal Industry and Fisheries (MAAIF) raised concerns to Cabinet about the Regulation of veterinary medicinal products, biological, chemicals and devices. Since the products under question were part of the NFDA Bill, the Bill could then not be presented to Cabinet until issues raised by MAAIF were resolved.

A Cabinet Sub-Committee under the leadership of the Office of the Prime Minister (OPM) was put in place to harmonize the positions of MAAIF, MOH and other key stakeholders.

A report of the Cabinet Sub-Committee, with a harmonized position of the key stakeholders was developed. The Cabinet sub-Committee attained consensus on

issues raised by MAAIF. This report is to be presented to Cabinet together with the Bill.

Rt. Hon. Speaker and Hon. Members, as per the foregoing, my Ministry has lost a valuable time in the process of harmonizing different positions of key stakeholders. However, it was important for us to achieve consensus by stakeholders to enable the Bill drafting process to proceed smoothly.

Rt. Hon. Speaker and Hon. Members,
Allow me to throw more light on some of the regulatory gaps and issues we continue to grapple with in the absence of the NFDA Law

a. The current National Drug Policy & Authority (NDP& A) Act does not explicitly provide for regulation of cosmetics, medical/veterinary devices, public health products, vaccines, blood and biological products.

b. Some cosmetics are known to contain banned chemicals that are hazardous to human health e.g. mercury containing skin lightening creams. Further still, a number of drugs are found in ordinary shops being sold as cosmetics yet majority of these contain steroids which are Prescription Only Medicines (POM). Abuse of steroids is associated with various health problems for example diabetes, hypertension, kidney damage and heart disease.

c. Medical devices range from simple tongue depressors and bedpans to complex programmable pacemakers with micro-chip technology and laser surgical devices. They also include electronic radiation emitting products such as diagnostic ultrasound products, x-ray machines and medical lasers. Unregulated use of these devices, some of which are sub-standard compromise public health of Ugandans..

d. Blood products such as serum, antibodies, hormones are categorized as pharmaceutical products and if not effectively regulated can pose a risk to patient safety. E.g. transmission of highly infectious blood-borne diseases like

HIV/AIDS, Hepatitis B, Ebola; as well as causing diseases like hypertension, kidney damage and heart disease.

e. Special provisions relating to the regulation of veterinary drugs are not well articulated. The current Act does not provide for the differences related to handling and dispensing of veterinary drugs and this may lead to their inadequate regulation.

f. The current NDA Act does not provide for effective enforcement and deterrent penalties. NDA does not have sufficient powers to effectively control illegal practices and counterfeits. The penalties are not sufficiently deterrent and this has partly encouraged recurrent breach of the law.

g. The Food and Drugs Act Cap 278 does not address the modern concepts of ensuring food quality and safety by use of preventive approaches, risk analysis, precautionary principles, traceability, implementing an alert system, responsibility of producers and consumers, and transparency. As a result, Uganda experiences recurrent outbreaks of food related diseases.

h. A multi-agency food control system with no central coordination has resulted in a fragmented food safety and quality infrastructure resulting in duplication of roles and misuse of scarce government resources. This calls for a one stop-centre regulator for food.

i. Food safety issues are also potential threats to human/animal health in relation to biosecurity and bioterrorism (Food defense), genetically modified foods (GMO), and socio–economic sabotage to the food industry. These require regulation at critical control points in the food chain.

j. National and global biosecurity (food defense) concerns because food borne pathogens, parasites and chemicals are key target agents for intentional food contamination or potential agents for biological warfare and bioterrorism.

Rt. Hon. Speaker of Parliament and Hon. Members,

As I have mentioned above, the National Food and Drug Authority Bill has been subjected to extensive stakeholder consultations since 2009. The last round of consultations were conducted under the oversight of the Office of the Prime-Minister during which a Cabinet Sub-Committee was established to consider stakeholder interests in the Bill.

Therefore, based on the fact that extensive consultations have been made on the Bill and Government resources have already been spent with respect to this assignment, it is not necessary at this time to introduce a Private Member's Bill on a matter that is already under consideration by Government. It is pertinent to leverage ongoing Government efforts by supporting the progression of the National Food and Drug Authority Bill to Parliament; and finally enactment into a Law.

Rt. Hon. Speaker and Hon. Members,

In conclusion, allow me to reiterate the commitment of the Ministry of Health in safeguarding public health by putting in place supporting policies and a regulatory framework that will ensure effective regulation of food, medicines and healthcare products. My ministry is committed to progressing the Bill and calls for fast tracking of the enactment of this Bill into Law in order to safeguard the lives of Ugandans.

I do welcome the Honorable Member of Parliament, Hon. Mbwatekamwa Gaffa to join efforts with us and harness the ongoing work so that the Bill can be speedily enacted into Law

Thank you

Dr. Aceng Jane Ruth
MINISTER FOR HEALTH
REPUBLIC OF UGANDA

FOR GOD AND MY COUNTRY