

THE CONSTITUTION OF KENYA
REFUSAL TO ASSENT TO THE HEALTH LAWS
(AMENDMENT) BILL, 2018

MEMORANDUM

By His Excellency the Honourable Uhuru
Kenyatta, President and Commander-in-Chief of
the Kenya Defence Forces.

Submitted to the Speaker of the National
Assembly.

WHEREAS a Bill entitled “An Act of Parliament to make amendments to health-related laws”, the short title of which is “The Health Laws (Amendment) Bill, 2018” was passed by the National Assembly on the 7th November, 2018;

AND WHEREAS the Health Laws (Amendment) Bill, 2018, was presented to me for assent in accordance with the provisions of the Constitution, on the 31st December, 2018;

NOW THEREFORE, in exercise of the powers conferred on me by Article 115 (1) (b) of the Constitution, I refuse to assent to the Health Laws (Amendment) Bill, 2018, for the reasons set out hereunder:

PROPOSED AMENDMENTS TO THE PHARMACY AND POISONS ACT (CAP. 244)

SECTION 2

(a) New definition of the term “pharmaceutical device”

The Bill proposes to insert the definition of the term “pharmaceutical device” in section 2 of the Pharmacy and Poisons Act, which reads as follows:

“pharmaceutical device” includes human and veterinary medicines, medical products, medicinal substances, vaccines, diagnostics, blood products, therapeutic feeds, nutritional formulations, beauty products and related products;

The definition is identical to the definition of the term “health product”. Further, the term is not usually used internationally and is not aligned to the World Health Organisation (WHO). This may cause confusion in the application and affect international collaboration and trade.

RECOMMENDATION:

For the foregoing reasons, I recommend that the definition of the term “pharmaceutical device” be deleted.

(b) New definition of the term “pharmaceutical equipment”

The Bill proposes to insert the definition of the term “pharmaceutical equipment” in section 2 of the Pharmacy and Poisons Act, which reads as follows:

“pharmaceutical equipment” means equipment used in the manufacture and quality control of pharmaceutical products;

The term “pharmaceutical equipment” has not been used in either the Bill or the Act and therefore, the definition is redundant.

RECOMMENDATION

For the foregoing reason, I recommend that the definition of the term “pharmaceutical equipment” be deleted.

(c) New definition of the term “pharmaceutical product”

The Bill proposes to insert the definition of the term “pharmaceutical product” in section 2 of the Pharmacy and Poisons Act, which reads as follows:

“pharmaceutical product” means any material or product intended for human or veterinary use presented in its finished dosage or form, that is subject to control by or under this Act;

It is noted that according to the World Health Organization (WHO), the term “pharmaceutical product” normally refers to medicines or

drugs. The definition of the term “drug” has already be defined in the Act. This additional definition may cause confusion and affect international collaboration and trade.

RECOMMENDATION

For the foregoing reasons, I recommend that the definition of the term “pharmaceutical product” be deleted.

(d) New definition of the term “Good Manufacturing Practice”

The Bill proposes to insert the definition of the term “Good manufacturing practice” in section 2 of the Pharmacy and Poisons Act, which reads as follows:

“Good Manufacturing Practice” also known as “GMP” means a system for ensuring that products are consistently produced and controlled according to quality standards, and is designed to minimize risks involved in any pharmaceutical production that cannot be eliminated through testing the final product;

The proposed definition is not aligned to the World Health Organisation (WHO) meaning of “Good Manufacturing Practice”. This may cause confusion in the application and affect international collaboration and trade.

RECOMMENDATION

For the foregoing reasons, I recommend that the definition of the term "Good Manufacturing Practice" be deleted and replaced with the following:

"Good Manufacturing Practice" (GMP, also referred to as 'cGMP' or 'current Good Manufacturing Practice') is the part of quality management which ensures that products are consistently produced and controlled according to their intended use as required by the marketing authorization, clinical trial authorization or product specification.

SECTION 3

The Bill proposes to amend the Pharmacy and Poisons Act by deleting section 3 and replacing it with a new section 3. Paragraphs (2) (d), (e) and (f) of the proposed new section 3 read as follows:

"(d) one enrolled pharmaceutical technologist with expertise in community pharmacy appointed by the Cabinet Secretary;

(e) two persons representing the training institutions of which one shall be a pharmacist and one shall be a pharmaceutical technologist;

(f) three other persons appointed by the Cabinet Secretary, of whom—

(i) one shall be an enrolled pharmaceutical technologist nominated by the Kenya Pharmaceutical Association; and

(ii) two shall be registered pharmacists nominated by the Pharmaceutical Society of Kenya and one of whom shall have expertise in industrial pharmacy”

The effect of the proposed amendments is to establish a large and Board, contrary to the current Government policy of limiting the membership of Boards to manageable numbers and ensuring that while Boards containing core competencies and expertise, they do not become difficult to manage because of their sizes.

RECOMMENDATION:

For the foregoing reason, I recommend that paragraphs (d) and (f) be deleted, and paragraph (f) be replaced with the following new paragraph:

“(f) three other persons appointed by the Cabinet Secretary, of whom—

(i) one person shall be a pharmacist representing institutions of higher learning;

(ii) one person shall be a pharmaceutical technologist representing mid-level colleges;
and

(iii) one person shall be an enrolled pharmaceutical technologist with expertise in community pharmacy nominated by the Kenya Pharmaceutical Association”.

PROPOSED SECTION 3B

The Bill intends to insert new sections 3A and 3B immediately after section 3. Section 3B is intended to provide for the functions of the Pharmacy and Poisons Board. Parliament deleted paragraph (3) (g) and replaced it with a new paragraph (3) (g) which reads as follows:

“(g) approve institutions to be established or accredited under the Universities Act, 2012 for training of the pharmacy practitioners”.

The proposed amendment fails to take into account the oversight of mid-level training institutions that offer training for persons who intend to become pharmaceutical technologists.

RECOMMENDATION

For the forgoing reason, I recommend that the proposed paragraph (g) be deleted and replaced with the following new paragraph (g):

“(g) approve institutions to be established or accredited under the Universities Act, 2012 training pharmacists and mid-level institutions training pharmaceutical technologists”.

SECTION 24

The Bill did not initially propose any amendments to section 24 of the Pharmacy and Poisons Act. The House, however, amended section 24 of the Act by deleting the words “a pharmacist” and substituting therefor the words “pharmaceutical practice”.

The effect of the amendment is that poisons may be handled by persons who do not possess the requisite competencies to handle them, putting the public at grave risk.

RECOMMENDATION

For the foregoing reason, I recommend that the proposed amendment to section 24 of the Pharmacy and Poisons Act be deleted from the Bill.

PROPOSED AMENDMENTS TO THE MEDICAL PRACTITIONERS AND DENTISTS ACT (CAP. 253)

PROPOSED SECTION 4B

The Bill proposes to amend the Medical Practitioners and Dentists Act by inserting a new section 4B. Paragraph (f) of the proposed section 4B reads as follows:

(f) invest any funds of the Council not immediately required for its purposes;

The provision gives the Council unlimited power to invest any funds of the Council that are not immediately required for its purposes without reference to the Public Finance Management Act, 2012, which provides for the manner in which public funds may be invested. This may lead to the investment of public funds in a manner which is inconsistent with the Public Finance Management Act, 2012.

RECOMMENDATION

For the foregoing reasons, I recommend that the proposed paragraph (f) be deleted and replaced with the following:

(f) invest any funds of the Council not immediately required for its purposes, in accordance with the Public Finance Management Act, 2012 and other relevant laws.

PROPOSED AMENDMENTS TO THE NURSES ACT (CAP. 257)

(a)SECTION 4

Section 4 of the Nurses Act provides for the membership of the Nursing Council of Kenya. The Bill initially provided for the deletion of section 4 and its replacement with a new section 4 that included the Director General of Health as a member of the Council but the House deleted the proposal. The initial proposal in the Bill is in line with the current policy in respect of regulatory bodies in the health sector.

RECOMMENDATION:

For the foregoing reason, I recommend the amendment of the proposed new section for by inserting the following paragraph immediately after paragraph (1) (i):

“(j) the Director General of Health or a representative appointed in writing by the Director General of Health”.

(b) SECTION 9

Section 9 (1) of the Nurses Act provides for the functions and annual report of the Nursing Council of Kenya. Paragraph (i) provides:

- (i) to have regard to the standards of nursing care, qualified staff, nursing commodities, facilities, conditions and environment of health institutions, and to take such disciplinary or appropriate**

measures as may be necessary to maintain a proper standard of nursing care in health institutions;

The provision gives the Nursing Council of Kenya a mandate over standards of, among others, nursing commodities. The Bill initially proposed the deletion of the words “nursing commodities” in section 9 (1) (i) of the Nurses Act. The rationale for the proposal was the need to align the provision with the current policy of separating the regulation of commodities from the regulation of health professionals to increase efficiency, effectiveness and reduce the cost of doing business. The proposal was also intended to implement section 62 of the Health Act, 2017, which requires the establishment of a single regulatory body to regulate health products and health technologies. However, the amendment was rejected by the House thus the words remain in the Act.

RECOMMENDATION:

For the foregoing reasons, I recommend that section 9 (1) (i) of the Nurses Act be amended by deleting the words “nursing commodities”.

(c)SECTION 11

The Bill proposes to amend section 11 (5) of the Nurses Act by deleting the existing provision and substituting therefor the following new subsection:

(5) The officers appointed under this section shall be paid such remuneration and allowances as the Council may decide.

The amendment vests upon the Council the power to determine the remuneration and allowances of the officers appointed under the section, without reference to the Salaries and Remuneration Commission, which is mandated by Article 230 (4) (b) of the Constitution to advise on the remuneration of public officers. The provision contravenes Article 230 (4) (b) of the Constitution.

RECOMMENDATION:

For the foregoing reason, I recommend that the proposed section 11 (5) of the Nurses Act be deleted and replaced with the following:

(5) The officers appointed under this section shall be paid such remuneration and allowances as the Council may, on the advice of the Salaries and Remuneration Commission, determine.

PROPOSED AMENDMENTS TO THE COUNSELLORS AND PSYCHOLOGISTS ACT (NO. 14 OF 2014)

(a)SECTION 15

The Bill initially proposed the deletion of section 15 of the Counsellor and Psychologists Act, 2014 which provides for the

establishment of the Kenya Counsellors and Psychologists Society of Kenya. The rationale of the proposal was that the Society is a welfare organization that is independent of the Cabinet Secretary for Health. The Society ought to have been established under the Societies Act (Cap. 108). The proposal to delete the provision was rejected by the House.

RECOMMENDATION:

For the foregoing reasons, I recommend that the Counsellors and Psychologists Act, 2014 be amended by deleting section 15.

(b) SECTION 16

The Bill initially proposed the deletion of section 16 of the Counsellors and Psychologists Act which provides for the membership of the Society. The provision makes each person registered under the Act a member of the Society. The membership of each person who is registered under the Act is mandatory contrary to Article 36 (2) of the Constitution which provides for voluntary membership in associations of any kind. The provision contravenes Article 36 (2).

RECOMMENDATION:

For the foregoing reasons, I recommend that the Counsellors and Psychologists Act, 2014 be amended by deleting section 16.

(c) SECTION 17

The Bill initially proposed the deletion of section 17 of the Counsellors and Psychologists Act which provides for election of the chairperson of the Society in accordance with the Third Schedule and qualifications for election of the chairperson of the Society. The proposal was rejected by the House. However, as a consequence to the proposal that section 15 be deleted, a chairperson shall not be required.

RECOMMENDATION:

For the foregoing reason, I recommend that the Counsellors and Psychologists Act, 2014 be amended by deleting section 17.

(d) SECTION 18

The Bill initially proposed the deletion of section 18 of the Counsellors and Psychologists Act which provides for the functions of the Society. Section 18 (a) mandates the Society to establish standards of professional competence and practice among the members of the Society. This is a regulatory function, which ought to be the mandate of the Counsellors and Psychologists Board established under section 3 of the Act, as the regulator of counsellors and psychologists.

RECOMMENDATION:

For the foregoing reason, I recommend that the Counsellors and Psychologists Act, 2014 be amended by deleting section 18.

(e) SECTION 19

The Bill initially proposed the deletion of section 19 of the Counsellors and Psychologists Act which provides for Council of the Society. The proposal was rejected by the House. However, as a consequence to the proposal that section 15 be deleted, a Council of the Society shall not be required.

RECOMMENDATION:

For the foregoing reason, I recommend that the Counsellors and Psychologists Act, 2014 be amended by deleting section 19.

(f) SECTION 20

The Bill initially proposed the deletion of section 20 of the Counsellors and Psychologists Act which provides for the Committees of the Council of the Society. The proposal was rejected by the House. However, as a consequence to the proposal that section 15 and 19 be deleted, committees shall not be required.

RECOMMENDATION:

For the foregoing reason, I recommend that the Counsellors and Psychologists Act, 2014 be amended by deleting section 20.

(g) SECTION 21

The Bill initially proposed the deletion of section 21 of the Counsellors and Psychologists Act which provides for the

membership of the Council of the Society and their election in the manner prescribed in the Fourth Schedule. The proposal was rejected by the House. However, as a consequence to the proposal that section 15 and 19 be deleted, members shall not be required.

RECOMMENDATION:

For the foregoing reason, I recommend that the Counsellors and Psychologists Act, 2014 be amended by deleting section 21.

(h) SECTION 22

The Bill initially proposed the deletion of section 22 of the Counsellors and Psychologists Act which provides for the Secretary to the Council of the Society. The proposal was rejected by the House. However, as a consequence to the proposal that section 15 and 19 be deleted, the Secretary to the Council shall not be required.

RECOMMENDATION:

For the foregoing reason, I recommend that the Counsellors and Psychologists Act, 2014 be amended by deleting section 22.

(i) THIRD SCHEDULE

The Bill initially proposed the deletion of the Third Schedule to the Counsellors and Psychologists Act which provides for the manner of the election of the chairperson Council of the Society. The proposal was rejected by the House. However, as a consequence to the

proposal that section 15 and 17 be deleted, the procedure for the election of the chairperson shall not be required.

RECOMMENDATION:

For the foregoing reason, I recommend that the Counsellors and Psychologists Act, 2014 be amended by deleting the Third Schedule.

(j) FOURTH SCHEDULE:

The Bill initially proposed the deletion of the Fourth Schedule to the Counsellors and Psychologists Act which provides for the manner of electing the members of Council of the Society. The proposal was rejected by the House. However, as a consequence to the proposal that section 15, 19 and 21 be deleted, the procedure for the election of the members shall not be required.

RECOMMENDATION:

For the foregoing reason, I recommend that the Counsellors and Psychologists Act, 2014 be amended by deleting the Fourth Schedule.

PROPOSED AMENDMENTS TO THE CLINICAL OFFICERS ACT (NO. 20 OF 2017)

Section 4 (1)

The Bill proposes to amend section 4 (1) of the Clinical Officers Act, 2017 by deleting the provision and substituting therefor a new provision. The new paragraph (1) (a) reads as follows:

4.(1) The Council shall consist of the following persons—

(a) a chairperson to be appointed by the President who shall have—

(i) a relevant bachelors' degree from a recognized university; and

(ii) at least ten years' relevant experience;

This provision does not stipulate that the chairperson of the Clinical Officers Council shall be a clinical officer. This is unlike other legislation that establish regulatory bodies in the health sector which require that the chairpersons of the respective regulators come from their respective disciplines. There is need for clarity on who may be appointed as the chairperson of the Clinical Officers Council.

RECOMMENDATION:

For the foregoing reason, I recommend that the proposed paragraph (a) be amended by inserting the following new subparagraph immediately after subparagraph (a) (ii):

(iii) be registered as a Clinical Officer under this Act:

Further, the proposed paragraph (f) of section 4 (1), reads as follows:

(f) Two Clinical Officers representing universities training clinical officers elected amongst the teaching staff;

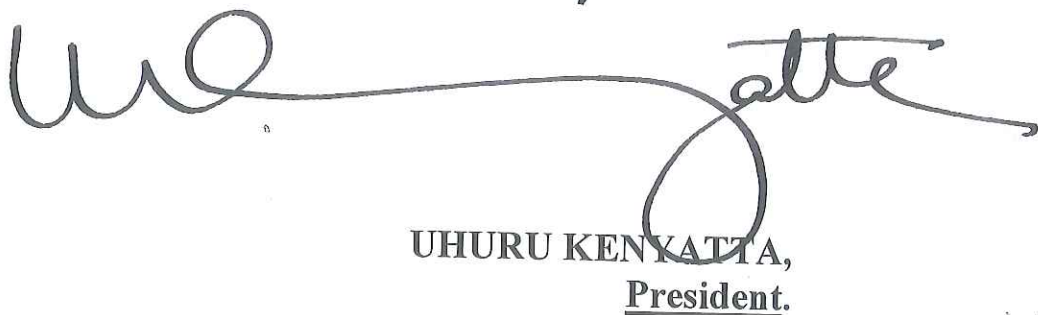
The proposed paragraph (f) provides for two representatives of universities in the Council resulting in the over-representation of university-level institutions in the Council, yet most clinical officers have been educated to the diploma level.

RECOMMENDATION:

For the foregoing reason, I recommend that the proposed paragraph (f) be deleted and replaced with the following:

(f) one Clinical Officer representing universities training clinical officers elected by the teaching staff from amongst their number;

Dated the 9th 9 January, 2019.


UHURU KENYATTA,
President.

