PARLIAMENT OF KENYA

THE SENATE

SENATE BILLS DIGEST

THE KENYA HEALTH PRODUCTS AND TECHNOLOGIES REGULATORY AUTHORITY BILL, 2022
(NATIONAL ASSEMBLY BILLS NO. 54 OF 2022)

Sponsor:	Senate Majority Leader (This is a National Assembly Bill sponsored by Hon. Robert Pukose, MP in the National Assembly)
Date of Publication:	10th November, 2022
Date of First Reading:	4th December, 2024
Committee referred to:	Standing Committee on Health
Type of Bill:	Ordinary Bill

1. PURPOSE OF THE BILL

The principal object of the Kenya Health Products and Technologies Regulatory Authority Bill, 2022 is to establish a framework to regulate health products and technologies to ensure their safety, quality, efficacy, effectiveness and performance. The Bill further establishes the Kenya Health Products and Technologies Regulatory Authority to, among other functions, regulate, investigate, inspect and approve health products and technologies.

2. BACKGROUND OF THE BILL

What is the problem that is sought to be addressed?

The regulation of pharmaceutical practice, drugs, therapeutic cosmetics, medical devices and related items is currently in fragmented legislation. This includes the Pharmacy and Poisons Board Act (Cap. 244) and the Narcotic Drugs and Psychotropic Substances Act (Cap. 254). The two Acts establish two separate entities (boards) to perform similar and overlapping functions. Further, the regulation envisaged in the said legislation is out of date and in dire need of review.

What does the law currently provide?

The Pharmacy and Poisons Board Act was enacted on 11th May, 1956 and amended numerous times, latest on 11th December, 2023. It establishes the Pharmacy and Poisons Board to, among others—

(a) formulate guidelines for regulating the manufacture, import and export, distribution, sale and use of medical products;
(b) grant or withdraw marketing authorization for medical products;
(c) grant or withdraw licenses to manufacturers, wholesalers, retailers, importers, exporters and distributors;
(d) prescribe the standards appropriate for new medical products, new uses, dosages, and formulations of existing medical products and such other categories as may be appropriate; and
(e) prepare a list of the substances which are to be treated as poisons.

The Act further provides for the registration and licensing of pharmacists, registration of premises carrying on pharmacy business, licensing of wholesale dealers in poisons and licencing of dealers in poisons for mining agricultural or horticultural purposes. The Act also establishes a National Quality Laboratory to, among others, examine and test drugs; perform chemical, biological, bio-chemical, physiological and pharmacological analysis and other pharmaceutical evaluation; and testing locally manufactured and imported drugs or medicinal substances.

On the other hand, section 16 of the Narcotic Drugs and Psychotropic Substances Act empowers the Cabinet Secretary responsible for matters relating to interior to establish a Board to—

(a) issue licences for the importation, exportation, diversion, sale, manufacture, production or distribution (at stated places) of any narcotic drug or psychotropic substance;

(b) name ports or places in Kenya where any narcotic drug or psychotropic substance may be exported or imported;

(c) prescribe the manner in which any narcotic drug or psychotropic substance is to be packed or marked for export; and

(d) prescribe the records to be kept by any person in connection with the export, import, receipt, sale, disposal or distribution of narcotic drugs or psychotropic substances

Section 17 of the Narcotic Drugs and Psychotropic Substances Act makes it a criminal offence, punishable by a fine not exceeding Kshs. 100,000/- or imprisonment for term not exceeding 5 years or both, for a person to—

(a) delay or obstruct any police officer or any person authorized by the Inspector General of Police, the Director of Medical Services or any other person in the exercise of any of their functions under the Act;

(b) wilfully destroy or mutilate or attempt to destroy or mutilate any document required to be produced before the relevant authority or a court under any provision of the Act;

(c) refuse or fails to produce or conceals, or attempts to conceal, any document or stock of narcotics or psychotropic substances where their production is required; or

(d) refuse or fail to comply with any lawful order or direction given by any public officer in the course of, or in connection with, the administration of any provision of the Act not being a noncompliance referred to in paragraph (c).

Section 18 of the Act further makes it a criminal offence, punishable by a fine not exceeding Kshs. 100,000/- or imprisonment for a term not exceeding 5 years or both, for a person to—

(a) fail or refuse to comply with any obligation to give or produce information required to be produced under Act;

(b) in purported compliance with any obligation to gives false information or documents required to be produced under the Act; or

(c) for the purpose of obtaining, whether for himself or any other person the grant or renewal of a licence or authority under this Act—

(i) make a false statement or gives false information; or

(ii) produce or otherwise make use of any record containing a statement knowing it to be false in a material particular or untrue.

Why the Bill?

The Bill seeks to create a robust and homogenous system to regulate health products and technologies. In keeping with international best practices and guidance from the World Health Organization, the aim of the proposed regulatory system is to safeguard the health of the public by ensuring the quality, safety and efficacy of all health technologies, medicines and related health products. This requires an institutional framework with a clear legal mandate and with the requisite expertise and independence in decision-making all contained in a single piece of legislation.

3. OVERVIEW OF THE BILL

What does the Bill regulate?

The Bill applies to the following products and technologies—

(a) medicines, medical products and technologies;
(b) medical devices including radiation emitting devices;
(c) radiopharmaceuticals;
(d) complementary, alternative and herbal medicines;
(e) cosmetics and borderline products;
(f) in-vitro diagnostics medical devices;
(g) therapeutic feeds;
(h) clinical trials;
(i) nutraceuticals and dietary supplements;
(j) digital health and technologies;
(k) scheduled substances;
(l) chemical substances; and
(m) biological products for use in humans and the starting materials used in their manufacture.

Oversight by the Kenya Health Products and Technologies Regulatory Authority

The Bill establishes the Kenya Health Products and Technologies Regulatory Authority whose primary objective would be to regulate, investigate, inspect and approve health products and technologies which is required to, among others—

(a) adopt and implement internationally recognized good regulatory practices;

(b) issue, suspend, withdraw or revoke any licence or compliance certificate required under the Bill;

(c) levy, collect and utilize fees for services rendered;

(d) grant or withdraw licences and permits to manufacturers, wholesalers, retailers, importers, exporters and distributions; and

(e) develop guidelines on the manufacture, import and export, distribution, sale and use of medical products.

Can a person sell, manufacture, supply, distribute or dispense any health products and technologies?

The Bill makes it an offence for a person to sell, manufacture, supply, distribute or dispense a health product or technology that is adulterated, substandard, falsified or not registered by the Kenya Health Products and Technologies Regulatory Authority. The offence is punishable—

(a) in the case of a first offence, to a fine not exceeding Kshs. 1,000,000/- or to imprisonment for a term not exceeding three months or to both; and

(b) in the case of a subsequent offence, to a fine not exceeding Kshs. 2,000,000/- or to imprisonment for a term not exceeding five years or to both.

Deception and falsification

The Bill makes it an offence for a person to falsify health products or technologies; label, package, treat, process, sell or advertise any health product or technology in contravention of regulations made under the Bill once enacted; or make statements regarding the character,

constitution, value, potency, quality, composition, merit or safety of a health product or technology in a manner that is false, misleading or deceptive. The offence is punishable—

(a) in the case of a first offence, to a fine not exceeding Kshs. 2,000,000/- or to imprisonment for a term not exceeding three years or to both; and

(b) in the case of a subsequent offence, to a fine not exceeding Kshs. 5,000,000/- or to imprisonment for a term not exceeding five years or to both.

Standards of health products and technologies

Where a standard has been prescribed or published with respect to a health product or technology, the Bill makes it an offence for a person to manufacture, label, package, sell or advertise any substance in a manner that the substance will be mistaken to have met the prescribed or published standard, undertake the processes in a with respect to a health product or technology under conditions that do not meet the prescribed standards or to manufacture, label, package, sell or advertise a health product or technology for which no standard is prescribed or published. The offence is punishable—

(a) in the case of a first offence, to a fine not exceeding Kshs. 1,000,000/- or to imprisonment for a term not exceeding three years or to both; and

(b) in the case of a subsequent offence, to a fine not exceeding Kshs. 2,000,000/- or to imprisonment for a term not exceeding five years or to both.

Registration of health products and technologies

The Bill requires a person who intends to import, manufacture or sell a health product or technology to apply to the Authority for registration of the product or technology in the prescribed form. The Bill thereafter empowers the Authority to register a health product or technology, upon application, once the Authority is satisfied of the safety, efficacy, quality, performance and economic value of the product or technology.

The Bill further empowers the Authority to issue a provisional certificate of registration for a health product or technology where it considers it necessary to protect public health or in the event of a threat to life or health.

The Bill also empowers the Authority to authorize a person to import or distribute, for a specified period and to a specified person or institution, a specified quantity of a particular health product or technology that is not registered. The Bill mandates the Authority to give notice in the *Gazette* of any registration or cancellation of the registration of a health product or technology;

Authorisation of health products and technologies

The Bill makes it an offence for a person to import a health product or technology unless the product or technology has been issued an import permit or a written authorisation by the Authority and the imported product or technology is inspected and verified by the Authority at the port of entry. The offence is punishable—

(a) in the case of a first offence, to a fine not exceeding Kshs. 1,000,000/- or to imprisonment for a term not exceeding two years or to both; and

(b) in the case of a subsequent offence, to a fine not exceeding Kshs. 2,000,000/- or to imprisonment for a term not exceeding five years or to both.

Can a registered health product or technology be de-registered?

The Bill also empowers the Authority to cancel the registration of a health product or technology where—

(a) a licensee has failed to comply with a condition subject to which a particular health product or technology has been registered;

(b) a particular health product or technology does not comply with a prescribed requirement; or

(c) it is not in the public interest to make a particular product or technology available to the public.

Generic substitutions

The Bill empowers a pharmacist or an enrolled pharmaceutical technologist, in consultation with the person prescribing the health product or technology and the patient, to dispense an

interchangeable multi-source health product or technology instead of the product or technology prescribed by the registered health professional.

Clinical trials

The Bill prohibits the use of a health product or technology for clinical trials without the approval of the Kenya Health Products and Technologies Regulatory Authority.

Scheduled substances

The Bill mandates the Authority to prepare and submit to the Cabinet Secretary lists of substances to be treated as scheduled substances. The lists are to include—

(a) substances which, subject to Bill once enacted, are not to be sold except by authorized sellers of scheduled substances and licensed wholesale dealers;

(b) substances which, subject to Bill once enacted, are not to be sold except by persons specially licensed to do so; and

(c) any other substance declared to be a scheduled substance by the Authority.

The Bill empowers the Authority to issue a licence to deal as a wholesale dealer in schedules substances, upon application, once the Authority is satisfied that it is in the public interest to issue the licence. The Bill further mandates authorized sellers of scheduled substances to record all sales before delivery of the substances. The Bill also makes it an offence for a person to supply scheduled substances in a container that is not labelled as prescribed, with offenders facing a fine not exceeding Kshs. 1,000,000/- or imprisonment for a term not exceeding 1 year or to both.

Manufacture of health products

The Bill makes it an offence for a person to manufacture a health product without a licence issued by the Authority and g a fine not exceeding Kshs. 10,000,000/- or imprisonment for a term not exceeding 10 years or to both for commission of the offence.

Medical devices

The Bill mandates the Authority to keep a register of all medical devices approved by the Authority. The Bill further makes a person from selling a medical device that is not registered by the Authority or that is adulterated, is substandard, falsified, falsely labelled or counterfeited or which fails to comply with specifications.

National Pharmacovigilance Centre

The Bill mandates the Authority to establish a National Pharmacovigilance Centre to set up and manage the national pharmacovigilance and post marketing surveillance system.

National Quality Control Laboratory

The Bill establishes the National Quality Control Laboratory under the Authority to be used as the facility for —

a) examination and testing of health products and technologies;

b) performing chemical, biological, bio-chemical, physiological and pharmacological analysis and other pharmaceutical evaluation;

c) testing of locally manufactured and imported health products and technologies prior to market authorisation and redistribution and post-distribution;

d) providing technical support to local manufacturers and building their capacity regarding quality control of regulated products;

e) conducting investigations into the quality and safety of regulated products;

f) conducting research and training; and

g) developing and administering a data bank on quality assurance on behalf of the Authority.

Advertisement and labelling

The Bill prohibits the advertisement of health products and technologies without written permission from the Authority. The Bill further specifically prohibits the publication of

advertisements that refer to a health product or technology in terms which are calculated to lead to the use of the product or technology for procuring abortion.

The Bill also prohibits the selling of health products or technologies that consist of or comprise a substance recommended as a medicine unless there is the following is clearly written on the product or technology or label fixed to them—

(a) the appropriate designation of the substance so recommended or of each of the active constituents or of each of the ingredients from which it has been compounded; and
(b) in the case that the active constituents or ingredients are written, the appropriate quantitative particulars of the constituents or ingredients.

Administration and enforcement

The Bill empowers the Cabinet Secretary responsible for health, on the recommendation of the Authority, to prohibit or control the manufacture, sale, advertisement or possession of any secret, patent or proprietary health products and technologies.

The Bill empowers the Authority to procure relevant information from any person. It also mandates authorized or licensed sellers of scheduled substances, health products or health technologies to produce registration certificates and licences whenever required by a regulatory officer. The Bill empowers regulatory officers to enter relevant premises; stop, search or detain any relevant aircraft, ship, or vehicle; examine any relevant receptacle or package; examine any relevant books, documents or other records; and seize and detain any relevant heath product or technology. The Bill further makes it a criminal offence to obstruct or hinder a regulatory officer from performing their duties.

The Bill empowers regulatory officers to prosecute offences under it and further empowers courts, upon conviction of a person for an offence under the Bill, to order the relevant licence to be canceled.

The Bill repeals the Pharmacy and Poisons Boars Act and sections 16, 17 and 18 of the Narcotic Drugs and Psychotropic Substances Act. To that effect, the Bill provides that all the

assets, liabilities, agreements, pending proceedings and staff of the Pharmacy and Poisons Board and the National Quality Control Laboratory shall be transitioned to the established Kenya Health Products and Technologies Regulatory Authority.

4. CONSEQUENCES OF THE BILL

The Bill, once enacted, will ensure and safeguard the quality, safety and efficacy of all health technologies, medicines and related health products produced in or imported into Kenya. It will also make it easier for practitioners and the public to find, understand and implement the law regulating health products and technologies as they it will be contained in a single piece of legislation.

5. WAY FORWARD

What next?

The Bill was Read a First Time in the Senate on 4th December, 2024. Pursuant to standing order 145 of the Senate Standing Orders, the Senate Standing Committee on Health shall facilitate public participation and shall take into account the views and recommendations of the public when the committee submits it report to the Senate.

What is expected of the members of public?

The members of the public are expected to present their views to the Standing Committee on Health for consideration.

Note:

1. This Digest reflects the Bill as passed by the National Assembly and does not cover any subsequent amendments to the Bill made thereafter.
2. The Digest does not have any official legal status.