LEGAL NOTICE NO. 98

THE PHARMACY AND POISONS ACT

(Cap. 244)

IN EXERCISE of the power conferred by section 44(1) of the Pharmacy and Poison Act, the Cabinet Secretary for Health, in consultation with the Pharmacy and Poisons Board, makes the following Rules—

THE PHARMACY AND POISONS (AMENDMENT) RULES, 2022

1. These Rules may be cited as the Pharmacy and Poisons (Amendment) Rules, 2022. Citation.

2. The Pharmacy and Poisons Rules, hereinafter referred to as "the principal Rules" are amended in Rule 2 by inserting the following new definitions in their proper alphabetical sequence— Cap. 244.

"Act" means the Pharmacy and Poisons Board Act;

"applicant" means a person, organization, company or entity seeking approval to advertise or promote a medicine or medical device;

"batch" also referred to as "lot" means a defined quantity of starting material, packaging material or product processed in a single series of processes so that it is expected to be homogeneous;

"batch release", also referred to as "lot release" means the process of evaluation of an individual lot of a licensed vaccine by a national regulatory authority before giving approval for its release onto the market;

"biological therapeutic" means a class of medicines which are grown and then purified from large-scale cell cultures of bacteria, yeast, plant or animal cells and includes vaccines, growth factors, immune modulators, monoclonal antibodies and products derived from human blood and plasma;

"Board" means the Pharmacy and Poisons Board established under section 3 of the Act;

"claim" means any presentation which states, suggests or implies that a product has particular qualities relating to its origin, nutritional properties, nature, processing, composition or any other quality, and is capable of objective substantiation;

"general public" means a person other than a healthcare professional;

"general sale drug'' means any drug whose use does not need the direction or prescription by a medical practitioner, pharmacist, dentist or veterinary surgeon;

"health care professional" means any person who has obtained health professional qualifications and is licensed by the relevant regulatory body;

''herbal drug'' means a finished medicinal product containing

plant which has its preparation presented with a therapeutic or prophylactic claim and includes any preparation which, partly or wholly, contains a plant material;

"human and veterinary use" means any medicament or curative or preventive substance, whether proprietary or in the form of a preparation, used in both humans and animals;

"label" means a display of written, printed or graphic matter on a product, the immediate container or wrapper accompanying the product;

"marketing authorization" means an official authorization or registration of a product by the Board for the purpose of marketing it in Kenya after evaluation for safety, efficacy and quality;

"marketing authorization holder" means an entity that holds the marketing approval for a product;

"media enterprise" means an organization whose business involves the collection, processing and dissemination of news or news articles, or in entertainment and education through the media;

"medical claim" includes any statement that conveys information about the state or attributes of a product in respect of its therapeutic use in connection with the—

(a) diagnosis, treatment, mitigation or prevention of a disease, disorder, abnormal physical or mental state, or the symptoms thereof, in a human being or an animal;

(b) restoration, correction or beneficial modification of organic or mental functions in a human being or an animal; or

(c) disinfection in premises in which food and drugs are manufactured, prepared or kept, hospitals, equipment and farm houses;

"medium" means a newspaper, magazine, medical journal, television, radio, the internet, vehicle branding, poster, handbill, cinema, point of sale material, digital and social media, any form of projected light or sound recordings or any other means of communication;

"misleading information" means information that gives a wrong idea or impression;

"new chemical entity" means an active ingredient, including its salts or esters, that has not been approved by the Board for marketing in Kenya;

''prescription only health product '' means any product required to be dispensed only upon a prescription given by a medical practitioner, dentist or veterinary surgeon or any other person approved by the Cabinet Secretary;

"publication" means the act of making information, stories or pictures available to people in any medium including books, newspapers, magazines or electronic media;

"product" means a medicine, medical device or herbal drug;

"promotion" means any informal and persuasive activity by a manufacturing pharmaceutical company, distributor of medicines or a body appointed by any of them, which induces the prescription, supply, purchase or sale of any medicine; and

"promotional material" means any representation concerning the attributes of a product conveyed by any means for the purpose of encouraging the prescription, supply, purchase, sale or usage of a product.

3. The principal Rules are amended by inserting the following new rule immediately after rule 3A—

Importation of biological therapeutics.

3B. (1) A person shall not import any biological therapeutic without a valid import licence issued under rule 3.

(2) A consignment of imported biological therapeutics shall not be released into the market from the port of entry or any approved premises until it is evaluated and approved in accordance with this rule.

(3) Every batch of a licensed biological therapeutic imported into Kenya shall be evaluated by a person authorized by the Board before approving its release into the market.

(4) In undertaking the evaluation of a batch under subrule (3), the person authorized by the Board—

(a) shall evaluate whether the biological therapeutic meets the approved specifications and related provisions; and

(b) may review and test the sampled biological therapeutics and conduct an independent review of the summary protocol for each biological therapeutic.

(5) Upon evaluation of a batch of the imported biological therapeutic under this rule, the Board shall, on being satisfied of compliance, approve and issue a certificate of batch release into the market for the evaluated batch of imported biological therapeutic.

(6) A person who contravenes paragraph (2) commits an offence.

4. The principal Rules are amended by inserting the following new rule immediately after rule 4—

Exportation of biological therapeutics.

4A. (1) A person shall not export a biological therapeutic to a destination outside Kenya without a valid export licence issued under rule 4.

(2) A consignment of any biological therapeutic shall not be released for exportation to a destination outside Kenya until it is evaluated and approved in accordance with this rule.

(3) A person authorized by the Board shall evaluate every batch of a biological therapeutic to be exported before approving its release for export to a destination outside Kenya.

(4) In undertaking the evaluation of a batch under subrule (3), the person authorized by the Board—

(a) shall evaluate whether the biological therapeutic meets the approved specifications and related provisions;

(b) may review and test the sampled biological therapeutic including—

(i) conducting an independent review of the summary protocol for each biological therapeutic;

(ii) collecting and testing samples from each batch to be evaluated;

(iii) reviewing the literature regarding the manufacturing process, testing method, specifications and standards of the biological therapeutic; or

(iv) reviewing the standard operating procedures of source management on animal raw materials and proof of source of raw materials.

(6) Upon evaluation of a batch of any biological therapeutic to be exported under this rule, the Board may, on being satisfied of compliance, approve and issue a certificate of

batch release for exportation to a destination outside Kenya.

(7) A person who contravenes paragraph (2) commits an offence.

5. The principal Rules are amended by inserting the following new rule immediately after rule 16—

Manufacture of biological therapeutics.

16A. (1) A person shall not manufacture for distribution any biological therapeutic which is or may be used for the treatment of any human ailment without a valid licence issued under rule 16.

(2) A consignment of biological therapeutics manufactured pursuant to a licence issued under these Rules shall not be released for distribution unless the consignment has been evaluated and approved in accordance with this rule.

(3) A person authorised by the Board shall evaluate every batch of any biological therapeutic before it is released onto the market for distribution.

(4) In evaluating a batch under paragraph (3), the person authorized by the Board—

(a) shall evaluate whether it meets the approved specifications and related provisions; and

(b) may review and test the sampled biological therapeutic including—

(i) conducting an independent review of the summary protocol for each biological therapeutic;

(ii) collecting and testing samples from each batch which is to be evaluated;

(iii) reviewing literature regarding the manufacturing process, testing method, specifications and standards of the biological therapeutic; or

(iv) reviewing the standard operating procedures for source management on animal raw materials and proof of source of raw materials.

(5) Upon evaluation of a batch under this rule, the Board may, on being satisfied of compliance, approve and issue a certificate of batch release for distribution of the evaluated batch of manufactured biological therapeutic.

(6) A person who contravenes paragraph (2) commits an offence.

Insertion of new rules.

6. The principal Rules are amended by inserting the following new rules immediately after Rule 21—

Requirements for advertisement.

22. (1) A person shall not advertise any health product except with the written approval of the Board.

(2) An application for the advertisement of any health product shall be made to the Board in form 34 set out in the Schedule VIII and shall be accompanied by the fee stipulated in rule 19.

(3) A health product shall not be promoted or advertised through any media, including social media, unless it is registered by the Board.

(4) A person shall not take part in the publication of any advertisement or promotion referring to a drug, medicine, medical appliance or similar article in terms which in the opinion of the Board are considered to be exaggerated or to bear little or no relation to the pharmacological properties and action of the ingredients or components thereof.

(5) Any printed material shall be clearly labelled with the advertisement approval reference number of the Board as a footer or header; or at any other place that is easily identifiable by the Board and the general public.

(6) The name and contact details of the marketing authorization holder or manufacturing company shall be displayed on every print media.

(7) A person who contravenes subrule (1), (3), (4), (5) or (6) commits an offence.

Advertisement and promotion.

23. An advertisement or promotion includes any written, pictorial, visual or other descriptive matter or verbal statement with a medical claim designed to promote the prescription, supply, sale or consumption of a health product—

(a) appearing in any paper, newspaper, diary, calendar, business card or other print publication;

(b) appearing on any television, cinema, radio or social media;

(c) circulated through electronic mail, short message service or multimedia message;

(d) offering trials of the health product to members of the public;

(e) distributed to the members of the public as a branded item;

(f) undertaken through a telephone help line or point of sale material;

(g) effected through branding on a vehicle, building, bench or other similar medium;

(h) undertaken through a road show or other similar means; or

(i) through any other means that may introduce, publicize or raise the profile or public awareness or visibility;

(j) through the activities of a medical representative including detail aids and other printed material used by the medical representative to update members of the general public to promote purchase;

(k) through the provision of branded materials to promote the prescription, dispensing, supply, administration and use of products materials to be used in sponsored meetings;

(l) through the provision of medical information with product claims to the general public; or

(m) through all other sales promotion of a medical product and technology in whatever form, such as participation in exhibitions, the use of audio-cassettes, films, records, tapes, video recordings, radio, television, internet, electronic media or interactive data systems.

Threshold for advertisement or promotion.

24. (1) An activity shall not be construed as a health product advertisement or promotion if it is not designed to promote the sale or consumption of the product.

(2) Without prejudice to the generality of subrule (1), the following activities shall not be construed as health product advertisement or promotion—

(a) any factual, accurate or informative announcement or reference material concerning any licensed medicine relating to pack changes, adverse reaction warnings, trade catalogues or price lists which do not contain any product claim;

(b) any reply made in response to an individual enquiry from a healthcare professional in response to specific communication which is accurate, not misleading and is not promotional in nature;

(c) non-promotional information to the general public through a press conference, press announcement, television, any radio report or public relations activity;

(d) any summary of product characteristics, a patient information leaflet, public assessment report or direct response to a question;

(e) the mandated and registered packaging and pack information including the patient or prescriber information leaflet;

(f) a statement relating to human health or disease which does not make reference to a specific product; or

(g) matters relating to pricing, bonuses or incentives stipulated in any written law.

Prohibited advertisements.

25. (1) A health product or technology shall not be advertised or promoted unless it is registered by the Board.

(2) A person shall not promote—

(a) any off-label or unregistered indication;

(b) any health product or technology that bears a different packaging from that approved by the Board;

(c) any material sent under the guise of personal communication;

(d) any herbal or complimentary medicine that is not listed by the Board; or

(e) any medical cosmetics not listed or registered by the Board.

(3) A person shall not advertise or promote a health product by providing a private prescription form that is pre-printed with the name of the health product in the main body of the prescription.

(4) A health product shall be advertised on the header section of the prescription perforated from the main body.

(5) A clinical trial or safety study shall not be undertaken for the purpose of promotion or advertisement.

(6) Where companies jointly or individually promote a health product, each company shall certify and bear the responsibility of the promotional material or activity.

(7) An advertisement or promotion shall not contain a statement or visual presentation which may lead to or support any act of violence, criminal or illegal activity or appear to condone such act or activity.

(8) A person who contravenes subrule (1), (2),(3),(4), (5) or (7) commits an offence.

Advertisement to the general public.

26. (1) An advertisement to the general public shall meet the following conditions—

(a) general sales health products shall be advertised only to the general public.;

(b) pharmacy only health products shall be advertised to the general public only within the pharmacy or hospital premise;

(c) any prescription only medicine, medical cosmetic, medical device or herbal or complementary product shall not be advertised to the public unless at the point-of-sale and the advertising materials such as dummy boxes should be used within the confines of the pharmacy; and

(d) controlled, narcotic and psychotropic substances shall not be advertised to the general public in any format.

(2) Subrule (1) shall not apply to—

(a) the advertisement or promotion of a licensed vaccine granted emergency use authorization by the Board as part of a national government-controlled vaccination campaign; or

(b) any other licensed medicine or health technology used in a public health emergency in response to the suspected or confirmed spread of a pathogenic agent, toxin, chemical agent or nuclear radiation.

Advertisements to health care practitioners.

27. A promotional advertisement of any general sales or prescription only health product shall be directed towards healthcare professionals who are qualified to prescribe, dispense, handle or supply medicines.

Promotion and advertisement of medical devices.

28. (1) The promotion of a medical device may be conducted if—

(a) the medical device being advertised to the general public does not require prescription or professional intervention;

(b) a prescription only medical device and in-vitro diagnostics is being promoted to healthcare professionals; or

(c) the medical device has supply restrictions and the restrictions feature on the advertisement

(2) A medical device that is used only for research shall not be advertised to the general public.

(3) The promotion of a medical device shall not indicate that the medical device can prevent or reverse the physiological changes or

degenerative conditions brought about or associated with ageing.

(4) A person who contravenes any provision of this rule commits an offence.

Advertisement of herbal and complementary medicine.

29. (1) A person shall not promote or advertise a herbal or complementary medicine without the approval of the Board.

(2) A person shall not promote or advertise any herbal or complementary medicine unless the herbal or complementary medicine is listed or registered by the Board.

(3) A promotion or advertisement of any herbal or complementary medicine shall—

(a) be based on evidence of traditional use of a substance or product, or on scientific evidence categorized depending on the level of claim being made;

(b) contain indications that are true, valid and not misleading, and do not lead to unsafe or inappropriate use of the product;

(c) be based on evidence which relates to the whole product or the same active ingredients with similar dosage regimen, dose form and route of administration to the product and the ingredient for which the claim is being made;

(d) not imitate the general layout, text, slogan or visual presentation of another herbal medicine or conventional product in a manner likely to mislead;

(e) have cautionary labels or disclaimer statements displayed on the label of the advertisement material of the herbal medicine or complementary medicine;

(f) not contain words such as “magic” or “miracle’’ or an exotic description such as “upper potency” or such other words as to induce the daily or continuous use of the product; and

(g) not contain words like “most effective” “least toxic, “best tolerated” or other special status such as “herbal medicine

or related products of choice".

(4) A person who contravenes any provision of this rule commits an offence.

Vitamin supplements.

30. (1) An advertisement for vitamin supplements shall not state or imply that—

(a) good health is likely to be jeopardized solely because there is lack of dietary supplementation with vitamins; or

(b) the vitamin supplements are a substitute for a balanced diet.

(2) A person who contravenes paragraph (1) commits an offence.

Weight management claims.

31. (1) A claim for weight management, body slimming, fat burning or fat or starch blocking product shall —

(a) be made in conjunction with reference to sensible lifestyle factors including diet and exercise; and

(b) have a mark with a clear disclaimer stating that "this product has not been proven to burn fat or block starch".

(2) A person who contravenes subrule (1) commits an offence.

Advertisements targeting pregnant or lactating women.

32. (1) An advertisement targeted towards pregnant or lactating women shall not—

(a) suggest or recommend any medicinal product, with the exception of some vitamin or mineral supplements, for use by pregnant or lactating women; or

(b) convey a message that—

(i) the advertised medicine or medicinal product does not cause harm or risk;

(ii) it is routine practice for pregnant women to take the medicine or medicinal product; or

(iii) the development of the unborn baby would be affected if the product is not taken.

(2) A person who contravenes paragraph (1) commits an offence.

Advertisements for children.

33. (1) An advertisement that is targeted towards children shall not —

(a) be aimed principally or exclusively at children under the age of twelve years;

(b) show a child using, or within reach of a health product without adult supervision; and

(c) display the image of a child unless accompanied by the image of an adult.

(2) A person who contravenes paragraph (1) commits an offence.

Advertisements for the general public.

34. An advertisement intended for the general public shall—

(a) indicate the generic name of the drug, the brand name or trade name of the drug which shall be succeeded by the names of the active ingredients using international non-proprietary names in brackets or below the trade name;

(b) display approved indications for use and major precautions, contra-indications and warnings;

(c) provide the dosage regimen and maximum allowed daily dosage in cases of herbal and complementary medicines; and

(d) display the phrase "*Maumivu yakizidi pata ushauri wa daktari"* or "If symptoms persist seek medical advice" or a phrase with a similar meaning.

Advertisements for health care professionals.

35. A promotion or advertisement for health care professionals shall prominently display—

(a) the brand or trade name which shall be succeeded by the name of the active pharmaceutical ingredient using either the international non-proprietary name or the approved generic name of the drug;

(b) the content of any active ingredient per dosage form or regimen;

(c) the name of other excipients known to have an effect;

(d) the approved therapeutic uses, dosage form or regimen;

(e) summarised information regarding safety of the product;

(f) references to the current scientific literature, as appropriate; and

(g) the contact details of the marketing authorization holder, name and address of manufacturer or distributor on every print media.

Publication of advertisement standards.

36. The Board shall, from time to time, publish and enforce the advertisement standards.

Organizational websites and portals.

37. (1) A company or an organization that intends to conduct an online pharmacy and health product advertisement or promotion shall—

(a) be licensed by the Board;

(b) have two windows, one for healthcare professionals whose access shall be restricted and another one for the general public; and

(c) ensure that the website or portal is operated, maintained and regulated by an authorized market authorization holder, manufacturer, distributor or their appointed representatives.

(2) A person who contravenes subrule (1) commits an offence.

Websites and portals for the general public.

38. (1) Any advertisement conducted on a website or portal that is aimed at the general public shall —

(a) be approved by the Board prior to being uploaded on the portal or website;

(b) be used to advertise general sales health products, medical devices and the services that the website or platform provides;

(c) not include any reference to named prescription only medicines, including price information;

(d) ensure that casual browsers are not presented with advertising for specific prescription only medicines through text or small prints at the bottom of the home page;

(e) ensure that any page other than the landing page which the consumer chooses to access contains non-promotional information which is accurate, factual and scientific;

(f) provide the indicative price for a general sales product on the homepage only;

(g) not mention any prescription only medicine on the home page;

(h) provide a factual list of prices of prescription only medicines on pages other than the home page and the price list shall not include product claims or actively encourage viewers to choose a product based on the price;

(i) not highlight any special offer on the price of a health product on the website as they are likely to promote irrational use; or

(j) not give free offers of health products during advertisements competitions or bonanzas.

(2) A person who contravenes subrule (1) commits an offence.

Websites and portals for health care professionals.

39. Any advertisement conducted on a website or portal that is aimed at healthcare professionals shall—

(a) be approved by the Board;

(b) have restricted access and shall be conspicuously labelled ‘for healthcare professionals only”;

(c) not contravene any of the provisions of the Act;

(d) ensure that the content meant for information, education and awareness is technical, factual, current and consistent with the latest scientific literature;

(e) ensure that a journal which is published or posted on the internet and which is expressly stated to be for healthcare professionals is directed at persons who are qualified to prescribe or supply medicines and the promotions contained in the journal are restricted and comply with the law; and

(f) ensure that each section of the journal promoting medical products and technologies is clearly labelled "intended for healthcare practitioners only".

(2) A person who contravenes subrule (1) commits an offence.

Press releases and product launches.

40. (1) Any product advertisement conducted through a press release or a product launch shall—

(a) ensure that the press release for a new chemical entity or health technology innovation is allowed only once; and

(b) ensure that the use of a brand name is succeeded by the generic name.

(2) A person who contravenes subrule (1) commits an offence.

Promotional meetings.

41. (1) Any product promotion or advertisement conducted through a promotional meeting, scientific conference or a webinar shall—

(a) be submitted to the Board one month prior for approval;

(b) not be circulated as a promotional material whether at a national or international meeting before approval; and

(c) be preprinted with the approval reference number of the Board.

(2) A person who contravenes subrule (1) commits an offence

Obligations of marketing authorization holders.

42. A marketing authorization holder shall—

(a) ensure that the product conforms to quality, safety and efficacy standards and is registered or retained by the Board before subjecting it to any promotion and advertisement;

(b) provide product education and training to healthcare professionals to ensure the appropriate, safe and effective utilization of a particular type of medical technology;

(c) ensure that its medical representatives and marketing team track the validity of

approved samples and refrain from illegal and unauthorized practices in relation to product promotional activities;

(d) ensure that the information provided about a product is correct and in accordance with the Act, these Rules and any guidelines issued under the Act;

(e) ensure compliance with the following requirements if the marketing authorization holder is involved in any patient support program—

(i) no incentive, other than material that will enhance positive health outcomes and compliance, is provided to a patient who is involved in the support program;

(ii) the data collected from the support program shall not be used for any purpose other than to increase positive health outcomes and not for any promotional activity; and

(iii) the duration of the support program is appropriate for the disease state treated by the product; and

(iv) report any contravention of the law and collaborate and cooperate in sharing information.

Obligations of media enterprises.

43. (1) A media enterprise shall—

(a) only advertise a product that is registered, retained and granted approval by the Board for advertisement;

(b) reject advertising and promotional materials that are not approved by the Board; and

(c) comply with the requirements of Act, other regulations and Rules for advertisements and promotions and report and contraventions on the said laws.

(2) A person who contravenes subrule (1) commits an offence.

Advertising offences.

44. A person who contravenes any of the provisions of these Rules in relation to advertising or promotion of a health product commits an offence and is liable on conviction to the penalties prescribed in section 40 of the Act.

General penalties.

45. A person who commits an offence under these Rules for which no penalty is provided shall, on conviction, be liable to the penalties prescribed in section 51 of the Act.

7. The principal Rules are amended in Schedule VIII by inserting the following new form immediately after form 33—

Form 34

PHARMACY AND POISONS BOARD
Application for approval of promotion materials

Pharmacy and Poisons Board		Application form	FOM017/MIR/SOP/006
			Rev No
1.0	Company Details		
		Name of company	
		Registration No	
		Physical address	
		Building	
		Street/Road	
2.0	Applicant Information		
	Name of applicant		
	Registration number		
	Cadre		
	Telephone		
3.0	Responsible Person Information		
	Name of the officer		
	Registration No		
	Cadre		

Telephone			
4.0 Product Particulars			
legal category	Product	Reg No	Type of Media
5.0 Application check list			
A copy of the proposed advert			
Proof of payment			
Copy of reference materials			
Copy of previous approval			
6.0 Applicant Declaration			
…… ……declare that the information contained within this application is true and correct.		Date ……	
		Sign…….	
7.0 FOR OFFICIAL USE ONLY			
Product	Approval granted	Rejection granted	
Reason for Rejection			
Name of officer		Date	

Made on the 8th June, 2022.

MUTAHI KAGWE,
Cabinet Secretary for Health.