MEDICINES AND RELATED PRODUCTS ACT, 2014
MEDICINES AND RELATED PRODUCTS REGULATIONS, 2020

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MEDICINES AND RELATED PRODUCTS ACT, 2014

MEDICINES AND RELATED PRODUCTS REGULATIONS, 2020

IN EXERCISE of the powers conferred on the Minister under section 65 of the Medicines and Related Products Act, 2014, these Regulations are made.

PART I – PRELIMINARY

1. Citation

These Regulations shall be cited as the Medicines and Related Products Regulations, 2020.

2. Interpretation

In these Regulations unless the context otherwise requires -

"Act" means the Medicines and Related Products Act, 2014;

adverse drug reaction means a response to a medicine which is noxious and unintended and which occurs at doses normally used in man for the prophylaxis, diagnosis or therapy of disease or for the restoration, correction or modification of physiological function;

"adverse event" means any unfavourable and unintended sign including an abnormal laboratory finding, symptom, or disease temporally associated with the use of a medicine, whether or not considered related to this medicine;

"Agency" means the Medicines Control Agency;

"authorised officer" means a person authorised in writing by the Agency, the Minister or any other person authorised by the Agency to perform such under the Act or these Regulations;

"authorised person" means a person engaged in any activity involving medicines and related products that has the required licence or permit;

"batch or **lot"** means a defined quantity of a medicine or related product manufactured in a single manufacturing cycle and which has homogeneous properties;

"batch number or **lot number"** means a unique number or combination of numbers or codes allocated to a lot or a batch by the manufacturer;

"benefit-risk balance" means an assessment of the positive therapeutic effects of the medicine or related product in a relationship to its risks;

"bioequivalence" means the absence of a difference within the predefined acceptance criteria in the bioavailability of the Active Pharmaceutical Ingredient (API) or its metabolite at the site of action when administered at the same molar dose under similar conditions in an appropriately designed study;

"biologicals" mean a diverse category of medicines that are generally large, complex molecules including vaccines, blood and blood components, allergenics, somatic cells, gene therapy, tissues, and recombinant therapeutic proteins of human, animal, plant or microorganism origin. These medicines may be produced through biotechnology in a living system, such as a microorganism, plant cell, or animal cell, and are often more difficult to characterise than small molecule medicines;

"biosimilar product" means a biological product that is highly similar to and has no clinically meaningful difference from an approved biological product or reference product;

"bonded warehouse" means a system of public storage or warehouse established or authorised by the Customs and Excise Act 2010, where medicines and related products are stored;

"clinical trial" means any investigation in human subjects or animals intended to discover or verify the clinical, pharmacological and other pharmacodynamics effects of an investigational product, or to identify any adverse reactions to an investigational product, or to study absorption, distribution, metabolism, and excretion of an investigational product with the object of ascertaining its safety and efficacy, as defined by the International Council for Harmonisation;

"clinical trial or clinical study protocol" means a document that describes the objective, design, methodology, statistical considerations, and organisation of a clinical trial. The clinical study protocol usually provides the background and rationale for the trial, however, these could be provided in other protocol referenced documents;

"clinical trial or clinical study protocol amendment" means a written description of a change or formal clarification of a clinical trial or clinical study protocol;

"certificate or authorisation letter" means an authorisation certificate or letter issued by the Agency under these Regulations;

"compassionate use" means access to unregistered medicines and related products in special or emergency situations. In general, either the patient has a severe or life-threatening illness and existing therapy has failed, or the disease is a rare one for which specialist medicines do not have a local marketing authorisation. The medicines and related products are still experimental, or at any rate unproven, and the government is not obliged to fund their supply;

"container or package" means the material used in the packaging of a medicine and include primary and secondary packages and transportation containers. Containers are referred to as primary if they are intended to be in direct contact with the product and secondary containers are not intended to be in direct contact with the product;

"controlled medicine or controlled drug" means any medicine or other substance as listed in the United Nations Convention Against Illicit Traffic in Narcotic Drugs and Psychotropic Substances or as determined by the Agency;

"coordinating investigator" means an investigator assigned the responsibility for the coordination of investigators at different centres participating in a multicentre trial;

"counterfeit" means substandard and falsified and as defined in the Act under Section 38;

"dispensing" means the process of preparing and giving medicine to a named person on the basis of a prescription by a relevant health care professional as per the Schedules in these Regulations. It involves the correct interpretation of the wishes of the prescriber and the accurate preparation and labelling for use by the patient;

"dosage form" means the pharmaceutical form in which the active ingredients, excipients and physical formulation of a medicine is presented;

"efficacy" means the measurement of a medicine's desired effect under ideal conditions;

"Ethics Committee or Institutional Review Board" means a multidisciplinary body responsible for reviewing biomedical research for safeguarding the dignity, rights, safety, and well-being of all actual or potential research participants;

"expiry date" means the date up to which a medicine will retain the strength and other properties stated on the label which strength and other

properties can change after the lapse of time and after which date the medicine shall not be sold to the public or used;

"Executive Director" means the Executive Director of the Agency;

"generic medicine or multisource medicine" means a legitimately-produced medicine that is an exact copy of the originator product and performs the same way;

"good clinical practice" means a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate and that the rights, integrity, and confidentiality of trial subjects are protected;

"good manufacturing practices" means a code of standard practice concerning the production, processing, packing, release, and holding of a medicine which ensure that medicines are consistently produced and controlled according to quality standards appropriate to their intended use and as required by marketing authorisation;

"haemovigilance" means the set of surveillance procedures covering the entire blood transfusion chain, from the donation and processing of blood and its components, through to their provision and transfusion to patients including their follow-up. It also includes the monitoring, reporting, investigation, and analysis of adverse events related to the donation, processing and transfusion of blood, and taking action to prevent their occurrence or recurrence;

"harmonisation" means alignment or adjustment of differences and inconsistencies among different laws, Regulations, methods, procedures, schedules, specifications, or systems of National Medicines Regulatory Agencies or Authorities;

"health facility" means a publicly, privately-owned or non-governmental health institution that provides healthcare services to individuals;

"herbal medicine" means plant–derived materials preparations, with therapeutic or any other human or animal health benefits which contain raw or processed ingredients from one or more plants and materials of organic or animal origin;

"identification number" means the number obtained from a –

(a) birth certificate, passport, valid driver's licence,

(b) Gambian identification document, or

(c) any other relevant official document issued by the Government of The Gambia;

"informed consent" means a process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed and dated informed consent form;

"inspection" means the act by a regulatory authority of conducting an official examination of documents, facilities, records and any other resources;

"investigational medicinal product" means a pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial. For the purpose of these Regulations these may include related products under investigation as defined in the Act and these Regulations;

"investigator or sub-investigator" means a member of the clinical trial team designated and supervised by the principal investigator at a trial site to perform critical trial-related procedures or make important trial-related decisions and includes associates, residents, and research fellows;

"legal guardian" means a person who is the guardian of a child by virtue of the provision the Children's Act 2005 or a person lawfully appointed to be guardian of the child by Deed or Will or by an order of a court of competent jurisdiction or by operation of law;

"investigator's brochure" means a compilation of the clinical and nonclinical data on the investigational product which is relevant to the study of the investigational product in human participants;

"man" means a human being;

"manufacturer" means a person or corporate body manufacturing products regulated under the Act and these Regulations and includes a pharmaceutical manufacturing company;

"manufacturing" includes the operations involved in producing, preparing, formulating, treating, processing, filling, decanting, packaging, labelling and release of medicines;

"marketing authorisation holder" means a person in whose name a registration certificate has been granted and who is responsible for all aspects of the medicine or related product, including quality and safety and compliance with conditions of registration;

"medicines" means as defined in the Act and also includes biologicals as defined in these Regulations;

"medical device" means as defined in the Act and also includes software used alone or in combination for diagnosis, prevention, monitoring, treatment or alleviation of disease in humans or animals;

"misbranded" means labelling which is false, misleading, inaccurate or fails to provide information as required;

"Minister" means the Minister of Health;

"mutual recognition" means the acceptance of one National Medicines Regulatory Agency's certification of standards and procedures for medicines and related product regulation by another National Medicines Regulatory Agency;

"National Authorities" means the Customs and Excise, Drug Law Enforcement Agency of The Gambia, Police and State Intelligence Service;

"non-clinical study" means a biomedical study not performed on human subjects;

"non-interventional observational study" means a study in the context of which findings resulting from persons' treatment with medicines or related products are analysed using epidemiological methods. The treatment including the diagnosis and monitoring shall not follow a predetermined trial protocol but shall result exclusively from current medical practice;

"nutritional supplement" means products that contain one or more ingredients such as vitamins, minerals, herbs, amino acids or other nutrients that are intended in-

(a) the diagnosis, treatment, mitigation or prevention of disease, disorder of abnormal physical state or the symptoms of it, in man or animal, or

(b) restoring, correcting or modifying organic functions;

"parallel import" means importing a medicine without authorisation of the medicine registration holder from another country where it is legitimately located;

"participant" means the equivalent of subject or trial subject in these Regulations. Subject means an individual who participates in a clinical trial either as a recipient of the investigational medicinal product or as a control;

"patient information leaflet" means the information pertaining to a medicine as provided for in this Regulations, written in a manner which is easily understandable by the patient and as determined by the Agency;

"person" means a natural or juristic person;

"pharmacovigilance" means the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem;

"Pharmacy Act" means the Pharmacy Council Act 2014;

"pharmacy support personnel" includes Pharmacy Technicians, Dispensing or Pharmacy Assistants or Nurse Dispenser;

"principal investigator" means an investigator who is the responsible leader of a team of investigators who conduct a clinical trial at a clinical trial site;

"professional information" means the information about a medicine as provided for in these Regulations;

"proprietary name or **brand name** or **trade name"** means the name which is unique to a particular medicine or related product by which the product is generally identified and registered in the country of manufacture or in The Gambia;

"qualified person" means a professional who has the expert knowledge as determined in these Regulations and who is responsible for the compliance with technical and regulatory requirements related to the quality of finished products and the approval of the release of the finished products;

"quality" means the degree to which a set of inherent properties of a product, system, or process fulfils requirements as prescribed;

"restricted medicines and related products" means all medicines and related products scheduled in these Regulations and any other classification approved by the Minister;

"serious adverse drug reaction" means any untoward medical occurrence that at any dose-

(a) results in death,

(b) is life-threatening,

(c) requires inpatient hospitalisation or prolongation of existing hospitalisation,

(d) results in persistent or significant disability or incapacity, or

(e) results in a congenital anomaly;

"site master file" means a document prepared by the manufacturer containing specific and factual good manufacturing practice information about the production or control of pharmaceutical manufacturing operations carried out at a named site and any closely integrated operations at adjacent and nearby buildings;

"sponsor" means an individual, company, institution or organisation that takes responsibility for the initiation, management and financing of a clinical trial;

"unauthorised person" means a person engaged in any activity involving medicines and related products without the required licence or permit;

"unauthorised premise" means any premise used for activity involving medicines and related products without the required licence or permit; and

'wholesaler or **wholesale pharmacy"** means a person or corporate body who holds, stores, distributes or purchases medicines and related products from a manufacturer or supplier and sells them in accordance with the Act.

3. Categories and Classification of Medicines and Related Products

(1) All medicines and related products are categorised in the Schedules.

(a) Schedule 1 - OVER THE COUNTER MEDICINES (OTC), including NUTRITIONAL SUPPLEMENTS;

(b) Schedule 2 - PHARMACY MEDICINES (P);

(c) Schedule 3 - PRESCRIPTION ONLY MEDICINES (POM);

(d) Schedule 4 - HERBAL MEDICINES;

(e) Schedule 5 - VETERINARY MEDICINES;

(f) Schedule 6 - DIAGNOSTIC PRODUCTS/AGENTS;

(g) Schedule 7 - COSMETICS;

(h) Schedule 8 - HOMEOPATHIC MEDICINES;

(i) Schedule 9 - MEDICAL DEVICES;

(j) Schedule 10 - HOUSEHOLD CHEMICAL SUBSTANCES;

(k) Schedule 11 – LIST FOR PHARMACIES;

(l) Schedule 12 – LIST FOR DRUGSTORES; and

(m) Schedule 13 – LIST FOR SUPERMARKETS.

(2) The Schedules may be reviewed at any time as determined by the Minister on the advice of the Agency.

(3) The medicines and related products permitted for Pharmacies, Drugstores and Supermarkets are listed in Schedules 11,12 and 13.

4. Scope of these Regulations

(1) These Regulations shall apply to medicines and related products as defined in the Act and these Regulations, for human or veterinary use in the market, intended to be placed on the market or used in a clinical trial in The Gambia.

(2) The Agency shall publish guidelines on matters provided for in the Act or these Regulations for the purpose of giving guidance.

PART II - MANUFACTURING OF MEDICINES

5. Manufacture Licence

(1) A person shall require a licence issued by the Agency to manufacture medicines.

(2) Notwithstanding paragraph one, the following persons shall not require a licence-

(a) a pharmaceutical or research company or institute that is manufacturing, reconstituting or packaging medicines including their labelling according to quality standards as determined by the Agency intended for clinical trials in so far as this corresponds to the trial protocol;

(b) a hospital pharmacy authorised to distribute medicines, reconstituting or packaging including the labelling of medicines intended for clinical trials in so far as this corresponds to the trial protocol;

(c) the veterinary doctor operating a veterinary in-house dispensary for-

(i) the decanting, packaging or labelling of medicines without altering them,

(ii) the preparation of medicines from a finished medicine and medically non-active constituent, and

(iii) the mixing of finished medicines for the immobilisation of zoo, wild and reserve animals, in so far as these activities are undertaken for the animals in the veterinary doctors care;

(d) the wholesaler decanting, packaging or labelling medicines without altering them, provided the packages concerned are not intended for direct distribution to the consumer;

(e) the retailer who, in possession of the required expert knowledge, decants, packages or labels medicines without altering them for direct distribution to the consumer; and

(f) the decanting in an unchanged form for an individual patient, packaging or labelling of sera of non-human or non-animal origin authorised for marketing within the purview of the Act and these Regulations.

6. Application for a Manufacturing Licence

(1) An application for a licence to manufacture any medicine shall be made in the prescribed form to Agency and shall contain the -

(a) name and address both physical and postal of the applicant;

(b) name and registration number of the responsible pharmacist;

(c) contact details of the applicant including the telephone number and email address;

(d) address at which the manufacturing is to be undertaken; and

(e) estimated quantity of medicines that will be manufactured.

(2) The application shall include –

(a) a copy of the business registration certificate from the Registrar of Companies;

(b) a copy of the relevant degree certificate of the authorised person and proof of the required expert knowledge;

(c) qualifications of key personnel for quality assurance, quality control and production as determined by the Agency;

(d) the ability to comply with good manufacturing practice as determined by the Agency, which shall include-

(i) an inventory of equipment to be used in conducting the manufacturing and storage business, and

(ii) a manual of procedures and practices to be implemented to ensure the safety, efficacy and quality of medicines or related products to be manufactured or distributed and sold;

(e) payment of the prescribed application fee;

(f) a copy of the site master file;

(g) specific medicines to be manufactured;

(h) environmental impact assessment approval issued by the National Environmental Agency; and

(i) any other information as may be requested by the Agency.

7. Decision on Manufacturing Licence

(1) An application for a licence may be refused by the Agency where-

(a) at least one authorised person with the expert knowledge is not available in that specific area;

(b) the authorised person or the applicant is not competent to perform the job;

(c) a suitable premises and equipment for the intended manufacture, testing and storage of the medicines are not available;

(d) the manufacturer is not in a position to ensure that the manufacture or the testing of the medicines is carried out according to the acceptable standards prevailing in science and technology; or

(e) the manufacturer is not in a position to ensure that the manufacture is carried out in accordance with internationally recognised current good manufacturing practice as determined by the Agency.

(2) The Agency may approve and issue a licence if it is satisfied that the requirements of the Act and these Regulations have been complied with.

(3) The Agency shall keep a register of licensees and shall include -

(a) the licence number;

(b) the name of the licensee, physical and postal address of the premise and contact details; and

(c) the date the licence was issued for the first time.

8. Renewal and amending a Manufacturing Licence

(1) An application may be made by a licensee to the Agency to renew a manufacturing licence.

(2) The Agency may issue a new licence, provided that -

(a) the application is submitted with the prescribed form and the prescribed renewal fee;
(b) the original licence is returned to the Agency or an affidavit is submitted to the Agency stating that the original licence has been lost; and

(c) the Agency is satisfied that the application complies with provisions of these Regulations or any other conditions as may be determined by the Agency.

(3) An Applicant shall be provided within a period of 30 days from the day the application was submitted to address any objections underscored by the Agency.

(4) A licensee shall submit an application to the Agency, accompanied by the prescribed form and fee, to amend any of the details of the licence as follows -

(a) the location of the premises;

(b) the authorised person;

(c) the change in the name of the business;

(d) the change of the site address; or

(e) the list of medicines licensed to be manufactured.

9. Expert Knowledge

(1) An authorised person shall provide the following as proof of expert knowledge –

(a) for pharmacists, proof of registration with the Pharmacy Council of The Gambia;

(b) for pharmacists and non-pharmacist, a copy of a degree certificate in the relevant area of responsibility attained upon completion of accredited university studies or equivalent as determined by the Agency; and

(c) a period of at least five years practical experience in manufacturing of medicines or in the field of qualitative and quantitative analysis and other quality testing of medicines.

(2) In accordance with sub-regulation 1 (b), and authorised person shall provide evidence to the Agency that the university studies comprised theoretical and practical instruction in the relevant field of study.

10. Limitation of Manufacturing Licence

(1) The Agency shall issue a licence to an applicant for a specific factory site and for particular medicines and pharmaceutical forms of medicines.

(2) The licence shall include the authority to test medicines and active substances and the testing procedure is to be specified.

(3) A licence shall be valid for a specific period to be prescribed by the Agency.

11. Revocation and Suspension of a Manufacturing Licence

The Agency may revoke or suspend a licence –

(a) if it is known that one of the grounds for refusal existed at the time the licence was granted;

(b) for non-compliance with regulatory requirements; and

(c) if one of the grounds for refusal developed after the licence was issued.

12. Provisional Order

(1) The Agency may issue a provisional order to request the manufacturers to discontinue the manufacture of a medicine, if the manufacturer fails to furnish the Agency with evidence required for manufacture and testing.

(2) A provisional order may be restricted to one batch.

13. Areas of Responsibility

The authorised person shall -

(a) ensure that each batch of medicine is manufactured and tested in accordance with the Regulations applicable to the trade in medicines; and

(b) record the fulfillment of these provisions for each batch of medicines in a serially numbered register or comparable document before it is placed on the market.

14. Obligations to Notify

The Manufacturer or Marketing Authorisation Holder shall in writing-

(a) notify the Agency prior to any change in the information submitted to the Agency with the information proposed for change; and

(b) immediately notify the Agency of a change in the authorised person.

PART III - IMPORT, EXPORT OR STORAGE OF MEDICINES AND RELATED PRODUCTS, AND MANUFACTURE OF RELATED PRODUCTS

15. Application for a Licence

(1) An application for a licence shall be made to the Agency on the prescribed form and the prescribed fee for a licence to-

(a) manufacture a related product;

(b) import a medicine or related product;

(c) export a medicine or related product; and

(d) store medicines or related products in an appropriate storage facility or warehouse.

(2) The application for a licence shall include-

(a) a business registration certificate from the Registrar of Companies;

(b) a copy of an identification document;

(c) a copy of the certificate of registration of the responsible pharmacist with the Pharmacy Council The Gambia or a copy of the academic and professional registration certificate of the responsible person from the relevant statutory body;

(d) qualifications of other relevant personnel responsible for the manufacture of related products, as determined by the Agency;

(e) evidence of the ability to comply with current good manufacturing practices and good storage practices as determined by the Agency, and shall include-

(i) an inventory of equipment to be used in conducting the manufacturing and storage business, and

(ii) a manual of procedures and practices to be implemented to ensure the safety, efficacy and quality

of medicines, or related products to be manufactured or distributed and sold;

(f) the prescribed application fee; and

(g) any other information as may be requested by the Agency;

(3) The Application shall specify -

(a) the related products to be manufactured; or

(b) the medicines and related products to be imported, exported or stored for distribution and sale.

16. Terms and Conditions for Importation

(1) All medicines and related products imported into The Gambia shall–

(a) be registered in accordance with the Act;

(b) meet the conditions provided under section 36 of the Act; and

(c) be imported from a person or body corporate licensed by a regulatory authority recognised by the Agency.

(2) A person shall not import any medicine and related product into The Gambia unless he or she is issued with a permit by the Agency and shall submit -

(a) a completed application form obtained from the Agency;

(b) a copy of his or her identity document;

(c) a certificate of professional registration for practice where applicable;

(d) a certificate of incorporation and an operational licence where applicable; and

(d) one original and one copy of the certificates of analysis for each batch to be imported or a Certificate of Pharmaceutical Product issued by the regulatory authority of the exporting country.

(3) The Agency –

(a) may approve the application for import with or without conditions;

(b) shall where the application is approved, issue the applicant with a permit, valid for a period to be determined by the Agency; and

(c) may refuse to grant an application or may cancel a permit, where the holder fails to comply with the conditions of the permit.

17. Registration of Imported Medicine and Related Products

(1) A person issued with an import clearance permit shall apply to the Agency for the registration of any medicine or related product specified in the licence and shall submit to the Agency –

(a) a certified copy of the permit;

(b) the completed prescribed registration form;

(c) evidence of payment of the applicable application fee; and

(d) all other documents required for registration of the product.

(2) The Agency may, if satisfied that the application complies with the requirements for registration by the Act and these Regulations-

(a) approve the application with or without conditions; and

(b) issue the applicant with a certificate of registration in respect of such medicine or related product under the name approved by the Agency.

(3) The Agency may refuse an application where it is not satisfied that the application complies with the requirements of the Act and these Regulations.

(4) A person importing a medicine and related product in accordance with these Regulations shall immediately inform the Agency in writing of –

(a) any change in facts in the terms and conditions relating to which the application for a permit was issued;

(b) any amendments to the application for the registration of medicines and related products or the conditions for the registration of such medicine and related product; and

(c) the name of the holder of market authorisation in The Gambia for the import of the medicine or related product.

18. Ports of Entry

(1) The port of entry for imported medicines and related products into The Gambia shall be as follows-

(a) Banjul International Airport;

(b) Banjul Seaport; and

(c) by land at the following borders -

(i) Amdallai,

(ii) Farafenni,

(iii) Giboro, and

(iv) Sabi in Upper River Region.

(2) The border posts shall be officially secured by authorised officers as determined by the Agency.

19. Exceptions for Import

(1) Government hospitals, government health facilities and similar health-related institutions that provide healthcare services are authorised to import medicines and related products for use in patients undergoing treatment in its facilities.

(2) Non-Governmental Organisations, Private Clinics or hospitals including veterinary clinics or hospitals that provide healthcare services may be permitted by the Agency to import reasonable quantities for use only in patients under their care in their facilities and only if the products are not locally available.

(3) Registered Medical Doctors, Dentists and Veterinary surgeons may be permitted to import reasonable quantities on special request to the Agency for use only by patients under their care in their facilities and only if the products are not locally available.

(4) Patients with specific prescriptions for specialist medicines may import such medicines for their personal use only.

20. Import of Controlled Medicines

An application for a permit to import controlled, narcotic and psychotropic medicines including precursors shall be submitted to the Agency with the prescribed application form and shall contain the following information -

(a) the name, address and contact details of applicant;

(b) the name, address and contact details of the supplier;

(c) the name, address and contact details of manufacturer;

(d) a description of the product including proprietary and generic name, strength and dosage form;

(e) the unit of issue, total quantity, batch number and expiry date of the product;

(f) the registration number of the pharmacist or the responsible medical personnel;

(g) a copy of the registration certificate as required; and

(h) the consumption data.

21. Import Permit by Licensed Importers

(1) An application may be made to the Agency by licensed importers for a permit to import medicines and related products;

(2) An application shall be submitted with the prescribed form and with the prescribed fee and shall include the –

(a) name, address and contact details of the applicant;

(b) name and address of supplier;

(c) registration number of the supervising Pharmacist;

(d) contact details of the supplier, including the telephone number and email address;

(e) source of supply; and

(f) the place and the manner in which the medicines shall be stored safely.

(3) The applicant shall submit the list of the medicines and related products to be imported with details of the –

(a) description of the product including the proprietary and generic name, strength and dosage form;

(b) unit of issue and total quantity, batch number and expiry date of the products;

(c) invoice of the list of products; and

(d) name and address of manufacturer.

(c) The applicant shall provide consumption data on controlled medicines intended for import.

22. Application for Import for an Individual Patient

(1) An application for a permit may be submitted to the Agency by a medical practitioner for the import of a medicine and related product for the treatment, diagnosis or prevention of a medical condition for a particular patient.

(2) The application shall be submitted in the prescribed form and with the prescribed fee and shall include the -

(a) name and address of the medical practitioner;

(b) registration number of the medical practitioner with the Medical and Dental Council;

(c) contact details of the medical practitioner including the telephone number and email address;

(d) purpose for the application;

(e) name and physical address of the patient, dosage and period of treatment; and

(f) place and the manner in which the Scheduled medicines shall be stored.

(3) The applicant shall submit the list of the medicines and related products to be imported to the Agency with –

(a) a description of the product including proprietary and generic name, storage and dosage form;

(b) the unit of issue and total quantity, batch number and expiry dates of the products;

(c) the invoice of the list of products; and

(d) the name and address of the manufacturer.

(4) The applicant shall provide consumption data on the medicines and related products intended for import.

(5) The Agency may issue a permit for the import of limited quantities where the medicine and related product concerned is not available locally.

23. Medicines and Related Products for Use or Supply other than for Medicinal Purposes

(1) A person who intends to use or supply a medicine or related product for other than medicinal purposes shall apply to the Agency for a permit.

(2) The application shall include -

(a) the name, address and contact details of the applicant;

(b) the name and address of contact person;

(c) a copy of the national identification document of contact person;

(d) the qualifications of the contact person; and

(e) the purpose for the application.

(3) The Agency may issue the permit only where the medicine or related product concerned is not available locally.

(4) The applicant shall provide consumption data on the medicines and related products intended for use or supply.

24. Application by a Veterinary Doctor

(1) A veterinary doctor who intends to import a veterinary medicine and related product for the treatment, diagnosis or prevention of a medical condition in a particular animal shall submit an application to the Agency for a permit.

(2) The application shall contain at least the following information –

(a) name, address and contact details of the veterinary doctor;

(b) registration number of the veterinary doctor with the Veterinary Council;

(c) purpose for the application;

(d) the name and address of the owner of the animal, dosage and period of treatment; and

(e) the place and manner in which the veterinary medicine shall be stored safely.

(3) The applicant shall submit the list of the medicines and related products to be imported with details of the –

(a) description of the product including proprietary and generic name, strength and dosage form;

(b) unit of issue and total quantity, batch number and expiry dates of the products;

(c) invoice of the list of products; and

(d) name and address of the manufacturer.

(3) The applicant shall provide consumption data on the medicines and related products intended for import.

(4) The Agency may issue the import permit where the veterinary medicine and related product concerned is not available locally.

(5) A finished medicine that is not registered or authorised for sale on the market or exempted from authorisation or registration, may be imported and dispensed within the operating licence of the veterinary practitioner for use on animals under his or her practice.

25. Application for a Permit for Research

(1) An analyst, laboratory scientist or researcher who intends to import a medicine, diagnostic products, investigational product or veterinary medicine and other related products for the purposes of education, analysis, diagnosis or research, shall submit an application for a permit to the Agency.

(2) The application shall include-

(a) the name, address and contact details of the applicant;

(b) a copy of the identification document of applicant, if not registered by a professional body;

(c) a registration number of the applicant with a professional body, where applicable

(d) the name and address of the employer;

(e) copies of certificates of educational and professional qualifications of the applicant;

(f) particulars of the intended education, analysis, diagnosis or research project;

(g) the address at which the education, analysis, diagnosis or research will be conducted;

(h) the estimated duration of the project or activity;

(i) the total quantity of products to be kept in stock per annum;

(j) the source of supply; and

(k) the place and manner in which the medicine and related product shall be stored safely.

(3) The applicant shall submit the list of the medicines and related products to be imported with details of the -

(a) description of the product, proprietary and generic name, strength, and dosage form;

(b) unit of issue and total quantity, batch number and expiry date of the products;

(c) Invoice of the list of products; and

(d) name and address of the manufacturer.

(4) The applicant shall provide consumption data on the medicines and related products intended for import.

26. Application by a Private or Non-Governmental Health Facility

(1) The owner of a health facility who intends to import medicines and related products for the treatment, diagnosis or prevention of a medical condition in patients under its care shall submit an application for an import permit to the Agency.

(2) The application shall be submitted in the prescribed form and shall include-

(a) the name and address of the health facility or institution;

(b) a copy of the health facility licence or a copy of the Memorandum of Understanding;

(c) a copy of the professional registration certificate with the relevant authority;

(d) a copy of the Identification document of the responsible person working for the health facility;

(e) the contact details of the responsible health practitioner;

(f) the purpose for the application; and

(g) the place and manner in which the medicine and related product shall be stored safely.

(3) The applicant shall submit the list of the medicines and related products to be imported with details of the –

(a) description of the product, proprietary and generic name, strength and dosage form;

(b) unit of issue and total quantity, batch number and expiry date of the products;

(c) Invoice of the list of products; and

(d) name and address of manufacturer.

(4) The applicant shall provide consumption data on the medicines and related products intended for import.

(5) The Agency may issue a permit for the import of limited quantities where the medicine and related product is not available locally.

27. Application by a Government Health facility

(1) The Chief Executive of a Government health facility which intends to import medicines and related products for the treatment, diagnosis or prevention of a medical condition in patients in the Government health institution shall submit an application to the Agency for an import permit.

(2) The Application shall be submitted in the prescribed form and shall include the -

(a) name, address and contact details of the health facility; and

(b) place and manner in which the medicine and related product shall be stored safely.

(3) The applicant shall submit the list of the medicines and related products to be imported, with details of the-

(a) description of the product, proprietary and generic name, strength and dosage form;

(b) unit of issue and total quantity, batch number and expiry date of the products;

(c) invoice of the list of products; and

(d) name and address of the manufacturer.

(4) The applicant shall provide consumption data on controlled medicines intended for import.

(5) The Agency may in the case of a public health emergency grant an import permit to a government health facility.

28. Application for Import of Herbal Medicines, Nutritional Supplements and Related Products

(1) A person who intends to import -

(a) herbal medicines;

(b) nutritional supplements;

(c) medical devices;

(d) cosmetics; and

(e) household chemical substances,

shall submit an application for a permit to import to the Agency.

(2) The application for the permit shall be submitted in the prescribed form and shall include-

(a) the name and address and contact details of the applicant;

(b) the name, address and contact details of the supplier;

(c) reasons for import and the scope of operation;

(d) evidence of professional qualification where applicable;

(e) a copy of the applicant's personal identification document; and

(f) the place and manner in which the medicines shall be safely stored.

(3) The applicant shall submit the list of the intended products to be imported with details of the -

(a) description of the product, proprietary and generic name, strength and dosage form;

(b) unit of issue and total quantity and, if applicable, batch number and expiry date of the products;

(c) invoices of the products;

(d) name and address of manufacturer; and

(e) evidence of registration of the products intended for import.

29. Application for Import for Trial or Compassionate Use

The importation and use of unregistered medicines or related products for trial purposes or for compassionate use may be authorised by the Agency after submission of the relevant requirements for importation as determined by the Agency.

30. Inspection of Premises

All Permit holders shall be subject to regular inspections of their medicines and related products and premises by the Agency.

31. Medicines and Related Products for Personal Use

(1) A person who enters The Gambia whilst in possession of medicines or related products for personal use shall not require a permit from the Agency if –

(a) the quantity of medicines or related products does not exceed the quantity required for use for a period of up to six months or a period determined by the Agency; or

(b) the quantity of controlled medicines does not exceed the quantity required for use for a period of thirty days or a period determined by the Agency.

(2) A person referred to under sub-regulation (1)(b) shall provide the Agency with –

(a) the name, address and contact details of the licensed medical practitioner or dentist; and

(b) an original or a certified copy of the prescription for the medicine;

32. Import of Medicines and Related Products for Donation

(1) An application for a permit to import medicines and related products for donation shall be made to the Agency and shall include details of the -

(a) name, address and contact details of the applicant;

(b) name, address and contact details of contact person in The Gambia;

(c) source of supply;

(d) place and manner in which the medicines or related products shall be stored safely; and

(e) donation letter stating the purpose of donation.

(2) The Agency may issue a permit if the product complies with the applicable regulatory requirements and the quantity for donation is in accordance with the anticipated consumption within the expiry date.

(3) The applicant shall submit the list of the medicines and related products for donation with the -

(a) description of the product including the proprietary, generic name, strength, dosage form; and

(b) unit of issue and total quantity, batch number and expiry dates of the products.

(4) The applicant shall upon receipt of a permit, deliver all medicines and related products intended for donations to the intended institution.

(5) A person shall not remove any portion of the donation for personal use or for financial gains.

33. Prohibition of Substandard and Falsified Medicines and Related Products and Exemptions

(1) A person shall not import, export, supply, store, distribute, or sell any substandard and falsified or counterfeit medicines and related products or active substances in The Gambia.

(2) The Agency may make exceptions for the purposes of testing or for investigations in criminal prosecution.

34. Finished Products

Finished medicines and related products intended for use in human beings may be authorised for marketing or registered by the Agency-

(a) if they are to be procured and stored for emergencies, epidemics, national disasters in accordance with the Act and these Regulations; and

(b) shall be procured at short notice only where medicines for the therapeutic indication are not locally available.

35. Export, Re-Export and In- Transit Medicines and Related Products

(1) A person shall not export, re-export or transport in-transit medicines or related products unless -

(a) he or she is licensed as importer, wholesaler or local manufacturer;

(b) he or she is a registered Pharmacist or a person approved by the Agency as qualified to carry on the business; and

(c) the exportation, re-exportation or transport of in-transit medicines and related products is carried out in accordance with the conditions specified in the Act and these Regulations.

(2) An application for a permit shall be made to the Agency and shall include -

(a) the name, address and contact details of the applicant or company;

(b) the name and registration number of the responsible pharmacist;

(c) a copy of the professional registration certificate of the supervising pharmacist or authorised person;

(d) a copy of the appropriate licence issued by the Agency;

(e) the address where the medicines or related products will be stored nationally;

(f) the contact details of the recipient; and

(g) source of supply.

(3) The applicant shall submit the list of the medicines and related products with-

(a) a description of the products including the proprietary, generic name, strength and dosage form;

(b) the unit of issue, total quantity, batch number and expiry date of the medicines and related products;

(c) the invoice of the list of products;

(d) the name and registration number of the responsible pharmacist;

(e) the name and address of manufacturer; and

(f) the purpose of the application.

(4) The applicant shall provide the consumption data on all controlled medicines intended for export.

36. Medicines and Related Products on Transit

(1) Medicines and Related Products on transit through The Gambia shall–

(a) be stored in a bonded warehouse approved by the Agency; and

(b) not be tampered with or diverted while in the bonded warehouse unless approved by the Agency.

(2) Every bonded warehouse shall comply with good storage practices and approved conditions as determined by the Agency.

37. General Conditions for Manufacture, Import, Export, Distribution, Storage and Sale

(1) A person shall not use any premise for the manufacture, import, export, distribution, storage, packing or sale of any medicine or related product, unless-

(a) the premise is licensed by the relevant authority and complies with the conditions of the licence;

(b) the premise is kept illuminated by daylight or artificial light, at all times when any work is in progress;

(c) the premise is kept appropriately ventilated at all times for the storage of any medicine or related product or material for the packing of any medicine or related product;

(d) an appropriate waste management system has been installed;

(e) the premise is kept clean, free from foul odours, dust and organisms likely to contaminate the medicine or related product; and

(f) the walls, floors, ceilings, and roofs are properly constructed and kept in good repair.

(2) The premise shall-

(a) not be used for any other purpose than it is licensed for or may affect the quality of the medicine or related product;

(b) be equipped with sinks and other sanitary fittings necessary to cleansing appliances which shall be maintained in good and clean condition;

(c) be equipped with adequate supply of detergent, nail brushes, hot and cold water; and

(d) be fitted with washbasins and toilets for the use of persons employed on the premise.

38. Import, Export, Manufacture and Sale of Controlled Medicines or Substances

(1) A person shall not import, export, distribute, sell, manufacture or use in the manufacture of any controlled medicine or substance unless approved by the Agency and it is supplied with a return on or before 1st March of each year.

(2) The applicant shall provide the Agency with the required information to obtain approval and shall include the quantity of the substance -

(a) expressed in metric units, as a raw material or contained in a preparation, held in stock on 1st January of the preceding calendar year;

(b) acquired during the preceding calendar year by-

(i) importation, as a raw material or contained in a preparation,

(ii) production of the raw material in The Gambia, and

(iii) purchase of the raw material in or out of The Gambia with the name of the supplier;

(c) as a raw material or as contained in a preparation, which was disposed of during the preceding calendar year through exportation or destruction;

(d) used during the preceding calendar year in the production of any controlled medicine and the production of any other chemical substance; and

(e) preparations containing such substance remaining in stock on 31st December of the preceding year.

(3) The Agency may exempt an importer or exporter from providing a return if the particular return is not necessary to determine the consumption of any of the substances included.

(4) The applicant shall inform the Agency where the stocks are held or manufactured on behalf of another applicant.

39. Assistance of State Authorities

(1) The relevant state authorities shall assist the Agency in the supervision of the import and export of medicines, related products and active substances into The Gambia in accordance with the Act and these Regulations.

(2) A relevant state authority -

(a) may impound any consignments for inspection, as well as their means of conveyance, containers, loading and packing material; and

(b) shall immediately inform the Agency of suspected violations of prohibitions and restrictions of the Act or these Regulations in the execution of their duties.

40. Use of Medicines for Exhibition Purposes

(1) A manufacturer, importer, wholesaler, distributor, retailer, promoter or marketer, may use a medicine or related product as a sample for exhibition purposes or to introduce such a medicine or related product to healthcare providers or the public upon application for a permit made to the Agency.

(2) The samples shall –

(a) only be used for the purposes provided under sub-regulation (1); and

(b) not be handed out or given to any healthcare provider or member of the public unless clearance is issued by the Agency.

PART IV - RENEWAL OF LICENCE

41. Period of Validity and Renewal of a Licence

(1) A licence issued in accordance with the Act or these Regulations shall be valid for a period prescribed by the Agency unless -

(a) it is suspended; or

(b) revoked by the Agency in accordance with the Act or these Regulations.

(2) A licence granted in accordance with the Act or these Regulations may be renewed upon an application made to the Agency.

(3) An application for the renewal of a licence shall –

(a) contain the information or documentation prescribed in these Regulations;

(b) be accompanied by a fee prescribed by the Agency; and

(c) be made at least thirty days before the expiry of the existing licence.

(4) A licence referred to in these Regulations which has been revoked in accordance with the Act or these Regulations shall be immediately returned by the licensee to the Agency.

PART V - BATCH RELEASE FOR BIOLOGICALS

42. Registration of Biologicals

(1) An application to register biologicals manufactured outside of The Gambia shall be made to the Agency.

(2) The application shall include –

(a) the prescribed batch release fee;

(b) a number of samples for every batch;

(c) a copy of the protocol used to test the bulk batch and the filling batch; and

(d) a copy of the certificate of release issued by the national regulatory authority in the country the product was manufactured.

(3) An application to register biologicals manufactured in The Gambia shall be made to the Agency.

(4) The application shall include -

(a) the prescribed batch release fee;

(b) a number of samples for every batch; and

(c) a copy of the protocol used to test the bulk batch and the filling batch.

PART VI - REGISTRATION

43. Application for the Registration of a Medicine or Related Product

(1) A person who intends to register a medicine or a related product shall apply to the Agency in the prescribed form.

(2) The applicant shall submit the application with -

(a) the prescribed fee;

(b) a cover letter with a summary information including quantity and names of the products to be registered;

(c) the particulars of an expert with knowledge on the medicine or related product who shall communicate directly with the Agency;

(d) a proposed label for use on the medicine or related product, where applicable;

(e) a copy of the manufacture licence and the current good manufacture practice certificate from the regulatory

authority of the country where the medicine or related product is manufactured where applicable;

(f) data on the safety, efficacy and quality of the medicine or related product;

(g) samples of the medicine or related product submitted for registration;

(h) documentary evidence as required by the Agency to verify the existence of a manufacture site where applicable; and

(i) any other information as may be required by the Agency.

(3) All information submitted to the Agency shall be in English.

(4) All applications to register medicines or related products shall be submitted using the common technical document format or a format determined by the Agency.

(5) An application shall be made in respect of each individual dosage form and strength of a medicine or related product, where applicable.

(6) An application for the registration of a medicine or related product registered with an authority outside The Gambia shall be submitted with -

(a) a copy of the certificate of registration;

(b) professional information on the medicine or related product to be registered; and

(c) any other information as may be required by the Agency.

44. Registration of Veterinary Medicines

The provisions of Regulation 43 shall apply to the application for the registration of veterinary medicines.

45. Registration of an Interchangeable Multisource Medicine

(1) The Agency may on the application for registration of an interchangeable multisource medicine, determine any additional information to be submitted by the applicant.

(2) A medicine is considered therapeutically equivalent to another medicine if both medicines –

(a) contain the same amount of active substances in the same dosage form, meet the same or comparable standards and are intended to be administered by the same route;

(b) contain the same active moiety but differ either in chemical form of that moiety or in the dosage form or strength; and

(c) after administration in the same molar dose, their effects with respect to efficacy and safety are the same.

(3) Therapeutic equivalence is determined from comparative bioavailability, pharmacodynamics, clinical or in vitro studies; and

(4) The Agency shall determine the criteria for bioequivalence.

46. Particulars to be Published in the Gazette

The Agency shall cause to be published in the Gazette the -

(a) proprietary and generic name of all medicines registered by it;

(b) approved name and quantity of each active ingredient of the medicine contained in a dosage unit or per suitable mass or volume or unit;

(c) dosage form of the medicine;

(d) registration number allocated by the Agency;

(e) name and address of the manufacturer and marketing authorisation holder, if different from manufacturer; and

(f) Schedule of the medicine.

47. Register of Medicines

The Agency shall ensure that the register of medicines shall consist of the-

(a) proprietary and generic name of all medicines registered by it;

(b) registration number allocated to the medicine by it;

(c) approved name of each active ingredient of the medicine and the quantity thereof contained in a dosage unit or per suitable mass or volume or unit of the medicine;

(d) dosage form of the medicine;

(e) name of the marketing authorisation holder;

(f) name and physical address of the manufacturer(s) and the manufacturing facilities;

(g) date of registration of the medicine;

(h) Schedule of the medicine; and

(i) therapeutic class of the medicine.

48. Amendment of the Register

(1) A person who intends to amend an entry in the register shall apply to the Agency in the prescribed form.

(2) The application shall be submitted with the prescribed fee and shall consist of–

(a) the registration number allocated to the medicine by the Agency;

(b) the name of the marketing authorisation holder;

(c) the name and address of the manufacturer and the manufacturing facilities;

(d) a declaration by the holder of the marketing authorisation that the information furnished is complete and accurate;

(e) the terms of the amendment; and

(f) any other information as may be required by the Agency.

(3) Where a new certificate of registration is issued by the Agency –

(a) the original certificate of registration shall be returned by the applicant; or

(b) an affidavit shall be submitted to the Agency to confirm the loss of the certificate of registration.

(4) A certificate of registration for medicines shall be in a format as prescribed by the Agency.

49. Register for Controlled Medicines

(1) A person licensed under the Act or the Pharmacy Council Act 2014 to sell or dispense controlled medicines, shall keep a –

(a) record of relevant documents with the name and business address of the supplier or the receiver of the controlled medicine;

(b) copy of the import authorisation if the controlled medicines are imported; and

(c) register of the controlled medicines.

(2) The register shall consist of –

(a) the name, strength, quantity of controlled medicines available;

(b) the date on which the controlled medicine was received or supplied;

(c) the name and address of the person who purchased the controlled medicine;

(d) the name and address of the authorised prescriber where the controlled medicine is prescribed;

(e) the quantity of the controlled medicine or substance manufactured or used during the manufacture process, where the person is a manufacturer; and

(f) any other information as may be required by the Agency.

(3) The register shall be kept for a period of five years after the date of the last entry is made.

(4) Where the register is kept electronically, a monthly printout shall be made, signed, dated and filed in the records.

(5) All records shall be stored in an orderly manner.

50. Control of Medicines in Health Facilities

The responsible Pharmacist or authorised person shall supervise the safety, security, purchase, storage, compounding and dispensing of medicines in a health facility.

51. Timeframes for Considering Applications

(1) The Agency shall communicate the receipt of an application for registration of a medicine and related product in accordance with a timeframe to be determined by the Agency.

(2) The Agency shall communicate its decision on an application in accordance with a timeframe to be determined by the Agency.

52. Recall of Medicines and Related Products

(1) The Agency may issue an order to any importer, exporter, manufacturer, distributor or seller of any medicine or related product to -

(a) recall from sale, any medicine or related product or a portion of the produced quantity of any such medicine or related product, if the Agency believes on reasonable grounds that such action is necessary to protect the public;

(b) recall from sale, any medicine or related product or a portion of the produced quantity of any medicine or related product that does not conform to the specifications claimed for that medicine or related product;

(c) dispose of any medicine or related product, or any specific quantity of a medicine or related product, that has been directed to be recalled; or

(d) recall from sale, any medicine or related product or any portion of the produced quantity of any medicine or related product that is found to be substandard and falsified or counterfeit.

(2) The importer, exporter, manufacturer, distributor or seller shall, on receipt of an order made under Regulation 52 -

(a) inform the Agency of the manner and time the order will be complied with; and

(b) submit a written notice to the Agency immediately the order has been complied with.

(3) Notwithstanding any other provision, the Agency may issue directions to the recipient of an order to comply with an order, within the time provided and in a manner determined by the Agency.

(4) A recipient of an order shall cover all costs associated with the fulfilment of an order.

PART VII - PHARMACOVIGILANCE

53. Organisation of the Pharmacovigilance System

(1) There is established and operated by the Agency, a national Pharmacovigilance System.

(2) The National Pharmacovigilance System shall comprise -

(a) the National Pharmacovigilance Centre established under the Agency;

(b) Medicines Safety Experts Committee;

(c) regional and hospital investigation teams; and

(d) a focal person at the Regional Health Directorates and Health Facilities

(3) Key stakeholders of the National Pharmacovigilance System may include -

(a) a representative from the Ministry of Trade;

(b) a representative from the Ministry of Health;

(c) a representative from the Ministry of Agriculture;

(d) the Gambia Chamber of Commerce;

(e) health training institutions;

(f) health research institutions;

(g) manufacturers;

(h) suppliers;
(i) consumer associations;

(j) members of the media; and

(k) any other member as the Agency may determine.

(4) To prevent direct or indirect hazards to human health, the Agency shall -

(a) record and evaluate risks associated with the administration of medicines;

(b) record suspected cases of adverse drug reactions, interactions with other products, and adulterations and-

(i) monitor the outcome of the risk minimisation measures contained in the risk management plans, and

(ii) assess updates to the risk management system;

(c) record potential risks to the environment as a consequence of the use of a veterinary medicine; and

(d) co-ordinate the measures to be adopted to address any risks in accordance with the Act and these Regulations.

(5) The Agency shall cooperate with the World Health Organisation and other regional and international medicines regulatory authorities that keep records on medicines risks.

(6) The Agency shall inform the public about medicines that pose health risks and measures that have been developed to mitigate the risks.

(7) The Agency shall conduct regular audits of its Pharmacovigilance System.

54. Pharmacovigilance Inspections

(1) The Agency shall -

(a) inspect the collection and evaluation of risks of medicines and the co-ordination of necessary actions by the responsible persons; and

(b) may enter any premises during working hours, to inspect documents, the pharmacovigilance master file and request for any information as it may determine necessary for evaluation.

(2) The inspection shall apply to undertakings commissioned by businesses and facilities.

(3) The Agency shall prepare an inspection report for submission and comments to the health production business or facility.

(4) The Agency shall -

(a) inform the marketing authorisation holder if it fails to meet the requirements of the pharmacovigilance system; and

(b) provide details of any deficiencies detected during the inspection.

(5) The marketing authorisation holder shall provide to the Agency with a response to any queries detected during the inspection.

55. General Pharmacovigilance Obligations of the Marketing Authorisation Holder

(1) The marketing authorisation holder shall set up and operate a pharmacovigilance system.

(2) Where the marketing authorisation holder is not resident in The Gambia, he or she shall identify a local or regional agent to represent him or her.

(3) The holder of a marketing authorisation for medicines for human use shall -

(a) inform the Agency of any new or existing quality, safety or effectiveness concerns related to any medicine, including but not limited to adverse drug reactions;

(b) inform the Agency of any risk management activities;

(c) maintain a pharmacovigilance master file and make it available on request;

(d) evaluate all of the information, examine risk minimisation and prevention measures and, where necessary, take risk minimisation and prevention measures immediately based on its pharmacovigilance system;

(e) audit its pharmacovigilance system regularly at appropriate intervals; and make a note of the important findings in its pharmacovigilance master file and ensure that corrective

measures are taken to remedy deficiencies before the note is deleted from the pharmacovigilance master file;

(f) operate a risk management system for every medicine authorised and monitor the outcome of risk minimisation measures that are part of the risk management plan or as requested by the Agency; and

(g) update the risk management system and monitor pharmacovigilance data to determine whether there are any new risks, whether the risks have changed or whether there are any changes to the risk-benefit balance of medicines.

(4) The marketing authorisation holder for authorised medicines shall not make any pharmacovigilance information public without notifying the Agency and shall ensure that such information presented is not false or misleading.

56. Obligations of the Holder of a Marketing Authorisation for Medicines for Human use in the case of Suspected Adverse Drug Reactions

(1) The marketing authorisation holder shall keep a record of all suspected adverse drug reactions, the quantities supplied and -

(a) immediately inform the Agency of any suspected serious adverse drug reaction in The Gambia; and

(b) any suspected serious adverse drug reaction in any other country.

(2) The Agency may require the marketing authorisation holder to record suspected non-serious adverse drug reactions that occur in The Gambia.

57. Reporting Obligations of Health Professionals in the Case of Suspected Adverse Drug Reactions

(1) A health professional shall inform the Agency, in a manner determined by the Agency, of any new or existing quality, safety or effectiveness concerns related to any medicine, and shall include suspected adverse drug reactions.

(2) The Agency shall submit the received adverse drug reaction reports to the Medicines Safety Expert Committee for evaluation and recommendation.

(3) Where the Agency receives a recommendation and determines that the medicine may not be safe for use, it shall require the Licence holder to submit any additional information it considers necessary.

(4) The health professional shall maintain and provide the Agency with adverse drug reaction data records.

(5) These Regulations shall not prejudice any person from reporting any adverse drug reaction or any other safety, quality or effectiveness concern related to any medicine to the Agency.

(6) Safety reporting for veterinary medicines -

(a) it shall be the responsibility of the veterinary professional to report to the Agency risks associated with the administration of veterinary medicine, in particular adverse drug reactions, interactions with other products, adulterations as well as potential risks to the environment in accordance with the Act and these Regulations; and

(b) the Veterinary Council shall collaborate with the Agency in accordance with the requirements of the World Organisation for Animal Health.

58. Periodic Safety Update Reports

(1) The marketing authorisation holder shall transmit periodic safety update reports to the Agency in writing or electronically and shall include-

(a) a summary of the data that is of interest to assess the benefits and risks of a medicine, including the results of all studies that can have an effect on the marketing authorisation;

(b) a scientific evaluation of the medicine's risk-benefit balance based on all of the available data, including data from clinical trials for therapeutic indications and population groups that are not covered by the marketing authorisation; and

(c) data related to the medicine's volume of sales and any other relevant to the volume of prescriptions, including an estimate of the number of persons using the medicines.

(2) The Agency shall transmit the periodic safety update reports to the Medicines Safety Experts Committee for evaluation and recommendations.

(3) The frequency for the submission of periodic safety update reports shall be specified in the marketing authorisation as follows -

(a) where a medicine has not yet been placed on the market, at least every six months after the marketing authorisation has been granted and until it is placed on the market; and

(b) where a medicine has been placed on the market, at least every six months during the first two years after it is first placed on the market and once a year after two years and three-yearly intervals thereafter.

(4) Based on the recommendations of the Medicines Safety Experts Committee, the Agency shall determine whether there are new risks, whether the risks have changed and whether there are changes to the risk-benefit balance of medicines and shall take the necessary measures.

59. General Prerequisites for Non-Interventional Post-Authorisation Safety Studies

(1) A marketing authorisation holder shall -

(a) report to the Agency, any non-interventional post-authorisation safety study that is conducted in The Gambia voluntarily;

(b) submit the protocol and progress reports to the Agency; and

(c) transmit the final report to the Agency within one year after data collection is completed.

(2) A marketing authorisation holder shall not conduct non-interventional post-authorisation safety studies if -

(a) the study promotes the use of the medicine;

(b) payments for the participation of the health professionals involved is not restricted to compensation for time and expenses incurred; and

(c) an incentive is created for the preferential prescription or recommendation of specific medicines.

60. Special Prerequisites for Imposed Non-Interventional Post-Authorisation Safety Studies

(1) A marketing authorisation holder shall in the case of non-interventional post-authorisation safety studies conducted in The Gambia, submit to the Agency the draft study protocol for transmission to the Medicines Safety Experts Committee for evaluation and recommendations.

(2) A non-interventional post-authorisation safety study may only be commenced if the draft protocol has been authorised by the Agency based on the recommendations of the Medicines Safety Experts Committee.

61. Exceptions

The provisions of this Part shall not apply to medicines that are used as investigational medicinal products within the framework of a clinical trial.

PART VIII - PACKAGING AND LEAFLETS

62. Labelling of Medicines Intended for Human Use

(1) The primary or secondary container of every medicine intended for use by humans shall bear a clearly written and legible label in English language and include –

(a) the proprietary and generic name of the medicine clearly written;

(b) dosage form and strength of the medicine clearly indicated;

(c) the approved name of each active ingredient of the medicine and the quantity contained in a dosage unit, or per suitable mass or volume or unit;

(d) excipients that have a recognised action or effect as determined by the Agency and all excipients, if the medicine is injectable or a topical or eye preparation;

(e) the presentation and pack size expressed in the appropriate unit or volume of the medicine;

(f) instructions for use prior to intake of the medicine where applicable;

(g) the method, and if necessary route of administration by means of suitable words or abbreviations;

(h) the batch or lot number of the medicine;

(i) the manufacture and expiry date of the medicine in a font size that is clear and visible;

(j) the name and address of the manufacturer and marketing authorisation holder of the medicine;

(k) instructions for the storage of the medicine with specific reference to the applicable storage temperature and other precautions required for the preservation of the medicine;

(l) special or cautionary warnings as applicable;

(m) the registration number of the medicine allocated by the Agency;

(n) the active substance and the name of the genetically modified micro-organism or cell line used in its manufacture in the case of medicines produced using genetic engineering; and

(o) any specified warnings to be provided on the label of the medicine as a condition of registration determined by the Agency.

(2) The Agency may on application submitted to it in respect of an interchangeable multisource medicine, determine additional information to be provided by the applicant.

(3) The label on the primary container, of a blister pack shall include the -

(a) proprietary and generic name of the medicine;

(b) dosage form and strength;

(c) name of the holder of the marketing authorisation;

(d) manufacture and expiry date; and

(e) batch or lot number.

(4) The display on the primary container of a small immediate packaging unit shall include the -

(a) proprietary and generic name of the medicine;

(b) strength of the medicine;

(c) route of administration;

(d) method of administration;

(e) expiry date;

(f) batch or lot number; and

(g) contents by weight and volume of unit.

(5) The Agency may authorise the inclusion of any special information on the label of a medicine that is not required by these Regulations to be included.

63. Labelling Requirements for Veterinary Medicines

(1) The primary and secondary container of every package containing veterinary medicine shall be sold with a label clearly and prominently displayed on the package in English language and shall include the -

(a) words "for animal treatment only";

(b) proprietary and generic name of the medicine;

(c) dosage form and strength of the medicine;

(d) approved name of each active ingredient of the medicine and the quantity thereof contained in a dosage unit or per suitable mass or volume or unit;

(e) excipients that have a recognised action or effect as determined by the Agency and all excipients, if the medicine is injectable or a topical or eye preparation;

(f) species of animal for which the medicine is indicated, as applicable;

(g) presentation and pack size expressed in the appropriate unit or volume of the medicine;

(h) instructions before use where applicable;

(i) method, and if necessary the route of administration by means of suitable words or abbreviations;

(j) batch or lot number of the medicine;

(k) manufacture and expiry date of the medicine;

(l) name of the manufacturer and holder of the marketing authorisation of the medicine;

(m) requirements for storage of the medicine with specific reference to the applicable storage temperature and other precautions required for the preservation of the medicine;

(n) special or cautionary warnings where applicable;

(o) specified warnings on the label of a particular medicine as a condition of registration of that medicine as prescribed by the Agency; and

(p) active substance and the name of the genetically modified micro-organism or cell line used in its manufacture, where a medicine is produced through genetic engineering.

(2) Where any medicine is intended for use in food-producing animals and the ingredients of the medicine or metabolites contains eggs, milk or the tissue of animals, a warning for the withdrawal period of the medicine shall be included on the packaging.

(3) In addition to the requirements under sub-regulation (1), a packaging may include the –

(a) registration number of the medicine allocated by the Agency;

(b) approved indications; and

(c) recommended dosage of the medicine.

(4) Where the primary container takes the form of blister packs and the requirements specified under sub-regulation (1) appear on the secondary container, the content on the packaging shall include the -

(a) proprietary and generic name of the medicine;

(b) dosage form and strength of the medicine;

(c) name of the manufacturer or holder of the Marketing Authorisation;

(d) expiry date; and

(e) batch or lot number.

(5) The label on the primary container of a small immediate packaging unit shall include the -

(a) proprietary and generic name of the medicine;

(b) strength of the medicine;

(c) route of administration;

(d) method of administration;

(e) expiry date;

(f) batch or lot number; and

(g) contents by weight and volume of unit.

(6) The requirements specified under regulation 63 (1) shall not apply to a medicine excluded by the Agency or to –

(a) any medicine sold by a veterinary practitioner in the course of his or her professional activities for the treatment of a particular animal; and

(b) any medicine sold by a pharmacist in accordance with a prescription issued by a veterinary practitioner for treatment of a particular animal, provided that such medicine shall be sold in a package clearly and prominently labelled with the -

(i) name of the medicine or the name of each active ingredient or constituent medicine;

(ii) name of the person that the medicine has been sold to and a description of the animals for which the treatment is intended;

(iii) directions for the use of the medicine;

(iv) name of the veterinary practitioner and the name and address of the pharmacist who conducted the sale of the medicine; and

(v) date of dispensing.

64. Professional Information or Summary of Product Characteristics for Medicines for Human use

(1) The professional information for medicines for human use shall be made available –

(a) in hard copy either separately or as an integral part of the package;

(b) in writing in English with a minimum legibility type size; and

(c) any other requirements specified in this regulation.

(2) The professional information referred to in accordance with sub-regulation (1) shall include the –

(a) proprietary and generic name of the medicine;

(b) dosage form and strength of the medicine;

(c) approved name of each active ingredient and the excipient of the medicine and the quantity of each active ingredient contained in a dosage unit, or per suitable mass or volume or unit;

(d) pharmacological action and clinical particulars with the sub-headings-

(i) pharmacokinetic and pharmacodynamic properties,

(ii) summary of relevant pre-clinical and clinical studies,

(iii) therapeutic indications,

(iv) interactions,

(v) use during pregnancy and lactation,

(vi) adverse drug reactions,

(vii) contra-indications,

(viii) special precautions for use, and

(ix) known symptoms of overdose and antidote;

(e) dosage and method of administration;

(f) special and cautionary warnings and effects on the ability to drive and operate machines;

(g) major incompatibilities;

(h) shelf life and where necessary after reconstitution of the medicinal product;

(i) consumption date after the immediate packaging is opened for the first time where applicable;

(j) special precautions for storage and disposal;

(k) nature and contents of the immediate container;

(l) the presentation and pack size expressed in the appropriate unit or volume of the medicine;

(m) name and address of the marketing authorisation holder;

(n) words "herbal medicine", "nutritional supplement" or "homeopathic medicine" in the case of a complementary medicine;

(o) published date of the information; and

(p) any other information considered necessary by the Agency.

(3) A person may apply to the Agency to –

(a) authorise the deviation from the format and content of the professional information prescribed as a condition of registration of a medicine;

(b) authorise the inclusion of any specified information not required by these Regulations; and

(c) determine under a particular heading the information to be furnished in respect of an interchangeable multisource medicine.

(4) The requirements of this regulation shall not apply to any medicine compounded or sold by a pharmacist or any other person who is licensed to compound and dispense medicines in the course of his or her professional activities for the treatment of a particular patient.

(5) The Agency may withdraw any indication for a medicine if it determines that the risk-benefit profile for the indication is not in the public interest.

65. Patient Information Leaflet

(1) Every medicine package shall contain a patient information leaflet attached to the primary container or inserted into the secondary container.

(2) The patient information leaflet shall be written in the English language with a minimum legibility type size and consist of the-

(a) proprietary and generic name;

(b) dosage form and strength of the medicine;

(c) approved name of each active ingredient and excipient of the medicine;

(d) the quantity of each active ingredient contained in a dosage unit, per suitable mass, volume or unit;

(e) excipients and details on those excipients that have a recognised action or effect as determined by the Agency;

(f) approved indications;

(g) the following general statements on the duty of the consumer to always inform the health care provider if taking any other medicine or pregnant or breast feeding, for advice before taking the medicine -

(i) contra-indications,

(ii) precautions for use,

(iii) special or cautionary warnings and effects on the ability to drive and to operate machines,

(iv) medicine interactions, and

(v) a general statement on the duty of the consumer to consult a medical practitioner prior to the consumption of the medicine;

(h) dosage;

(i) method and route of administration;

(j) frequency and duration of treatment;

(k) side effects;

(l) instructions on how to consume the medicine;

(m) storage and disposal information;

(n) warning against using the product after the expiry date;

(o) name and business address of the holder of the marketing authorisation and the manufacturer;

(p) words "herbal medicine", "nutritional supplement" or "homeopathic medicine" in the case of complementary medicine;

(q) published date of the leaflet; and

(r) any other information as the Agency may determine.

66. Repackaging of Medicines into Patient Ready Packs

(1) The repackaging of a medicine shall be supervised by a registered pharmacist.

(2) The repackaging of a medicine shall be conducted by a -

(a) a Pharmacist;

(b) a Pharmacist Intern; or

(c) a Pharmaceutical Support Staff; and

(d) any other person authorised by the Agency to carry out the repackaging of a medicine.

(3) A batch numbering system shall be created to include all the information linking the repackaged medicine with the original packaging.

(4) The repackaging of a medicine shall be licensed by the Agency and carried out in accordance with good manufacturing practice.

PART IX - MARKETING OF MEDICINES AND RELATED PRODUCTS

67. Advertisement and Promotion of Medicines and Related Products

(1) A person shall not advertise or carry out any promotional activities for a medicine or a related product to the general public or health professionals as a treatment, diagnosis, prevention or cure for a disease, disorder or any abnormal physical state, unless the advertisement or promotional activity has been approved by the Agency.

(2) Medicines and related products listed under Schedules 1, 4, 7, 8, 9 and 10 may be advertised to the public after approval by the Agency.

(3) Medicines and related products listed under Schedules 2, 3, 5, and 6 may be advertised-

(a) for the information of health professionals; or

(b) in a health publication for health professionals.

(4) An advertisement for a medicine or related product shall not contain a statement relating to its safety, quality or efficacy that deviates from the evidence submitted to the Agency in the application for registration of a medicine or related product.

(5) An advertisement for a medicine shall contain –

(a) the proprietary and generic name of the medicine;

(b) the approved name and quantity of each active ingredient of the medicine, clearly and prominently written;

(c) where applicable an indication that the medicine is for veterinary use; and

(d) in the case of a complementary medicine -

(i) a statement to identify the discipline of the medicine, and

(ii) an indication that the medicine must be used in accordance with the applicable complementary discipline and principles.

PART X - ENFORCEMENT AND PENALTIES

68. Seizure and Quarantine of Medicines and Related Products

(1) A medicine or related product may be seized or quarantined by the Agency if it-

(a) is sold in contravention of the Act or these Regulations;

(b) is not registered in The Gambia;

(c) is substandard and falsified;

(d) has expired;

(e) is suspected to be stolen or smuggled into The Gambia;

(f) is sold-

(i) by an unauthorised person,

(ii) by an authorised person but in unauthorised quantities, or

(iii) at an unauthorised place or premise;

(g) has been declared unfit for use or consumptions in terms of the Act;

(h) belongs to the State and is found in an unauthorised non-government premise or in possession of an unauthorised person;

(i) is used in an unauthorised clinical trial; or

(j) is used for any unapproved purpose as determined by the Agency.

(2) A written inventory of all seized or quarantined items shall immediately be compiled after the inspection and shall include –

(a) the date, place and time of seizure or quarantine;

(b) the name and personal details of the person the items were seized or quarantined from;

(c) the details of every item seized or quarantined as determined by the Agency; and

(d) the name of the inspector conducting the inspection.

(3) Any item seized or quarantined may be used as evidence in any criminal proceedings in terms of the Act or these Regulations.

(4) Prior to the arrangement of a suspect before a court of competent jurisdiction, the Executive Director in consultation with the Board, may dispose of any seized medicine or related products in a manner to be determined by the Agency.

(5) The Agency may determine an illegally manufactured, imported, or unregistered medicine and related product to be a substandard and falsified product.

(6) A person shall not manufacture, import, store, distribute or sell substandard and falsified medicines and related products in The Gambia.

69. Method of taking Samples, Documents to be Issued and Reporting of Analysis Results

(1) An Inspector or authorised officer may take the required quantity of sample of a medicine or related product from a manufacturer, importer, distributor, wholesaler or retailer for analysis.

(2) The collection of the samples shall be –

(a) conducted in the presence of the person who is in charge of the medicine or related product or any witness;

(b) packed, sealed, labelled, transported and stored in such a manner to preserve the integrity of the medicine during the examination process; and

(c) accompanied with a document signed by the inspector.

(3) An Inspector or authorised officer shall record a written inventory of all samples obtained and shall include the-

(a) date on which, the place and time when the sample was obtained;

(b) description, nature and size of each sample obtained;

(c) personal details of the person in whose presence the sample was taken; and

(d) name of the inspector taking the sample.

(4) An Analyst shall, after receipt of the sample, test, examine or analyse the sample and submit a report of the results to the Agency.

(5) The Agency may require any holder of a Marketing Authorisation to supply the Agency with a sample of a particular medicine or related product in order to conduct an analysis.

(6) Reports and any other documents relating to these Regulations shall be submitted to the Executive Director within seven days from the date of receipt of the results.

(7) The cost of testing of samples shall be borne by the marketing authorisation holder or importer as the case may be or as determined by the Agency.

70. Offences and Penalties

(1) A person who contravenes any provision of the Act and these Regulations commits an offence and is liable on conviction to punishment in accordance with section 60 of the Act.

(2) The Executive Director in consultation with the Board may impose a fine of ten thousand dalasi and not exceeding two hundred thousand dalasi on any person who violates the provisions of these Regulations.

(3) A person who is dissatisfied with the decision of the Executive Director may appeal to the Minister within fourteen days from date of issue.

(4) The Agency shall introduce administrative fines or charges which shall be published in the gazette and may be subject to review as it deems necessary.

71. Compliance with Requirements

(1) All medicines and related products shall continue to comply with the standards and specifications submitted to and accepted by the Agency.

(2) Any proposed deviation from the accepted standards and specifications provided shall be submitted to the Agency for approval before use.

72. Investigations

The Agency may conduct an investigation on a medicine and related product in The Gambia where -

(a) such a medicine or related product is recalled in The Gambia or from any other country;

(b) any adverse drug reaction is reported;

(c) the medicine or related product is suspected or found not to comply with the requirements of the Act;

(d) there is an international alert with regard to such a medicine or related product; and

(e) for any other reason related to the safety, quality and efficacy of the medicine or related product, as the Agency may determine to investigate.

PART XI - CONDUCT OF CLINICAL TRIALS ON HUMANS

73. General Conditions for Clinical Trials

(1) A person shall not conduct a clinical trial of a medicine or related product without obtaining a favourable opinion of the Ethics Committee and the written authorisation of the Agency in accordance with section 39 of the Act.

(2) A person involved in a clinical trial of an investigational medicinal product on humans, shall fulfill the requirements of –

(a) good clinical practice provided under the International Council for Harmonisation guidelines for good clinical practice;

(b) the WHO guidelines for good clinical practice for trials on pharmaceutical products; and

(c) any other requirements to be determined by the Agency.

(3) A person may apply to the Agency in accordance with section 39 of the Act to conduct a clinical trial.

(4) The application shall be submitted with -

(a) a cover letter;

(b) the clinical trial protocol signed by the sponsor and principal investigator;

(c) the Investigator's brochure containing-

(i) pharmaceutical, pre–clinical pharmacological and toxicological data,

(ii) human or animal pharmacological, safety and efficacy clinical data about the investigational medicinal product, and

(iii) a certificate of analysis;

(d) summary of product characteristics or professional information for all registered medicines used in the trial, or the international equivalent where the medicines are not registered in The Gambia;

(e) the name, position and full contact details of the sponsor and principal investigators who will be responsible for the sites where the trial is to be conducted and shall be-

(i) registered with the relevant statutory health council, and

(ii) resident in The Gambia;

(f) a description of the professional qualifications and a copy of the educational certificates of all investigators, study pharmacists, statisticians, laboratory and data managers named in the trial protocol;

(g) proof of training in good clinical practice of all investigators named in the trial protocol as determined by the Agency;

(h) any previous training or experience obtained from work with clinical trials and patient care;

(i) a statement with any conditions, that may influence the impartiality of any of the investigators;

(j) proof of current, relevant and appropriate study insurance certificate issued by the insurance company or a copy of an indemnity provision for all participants in the clinical trials;

(k) details of the location where the trial is to be conducted including-

(i) a statement on the suitability of the clinical trial site relating to the nature and use of the investigational medicinal product, and

(ii) a description of the suitability of the facilities, equipment, human resources and expertise to be issued by the head of the clinic or person responsible;

(l) participant information sheet and informed consent form;

(m) proof of submission of the clinical trial application to the Ethics Committee in the case of a parallel submission;

(n) financial declaration of the trial that ensures adequate funding of the whole trial;

(o) the investigational medicinal product dossier where applicable and as determined by the Agency;

(p) the content of the labelling of the investigational medicinal products;

(q) good manufacturing practice certificate issued from the National Regulatory Authority of the country where the investigational medicinal products, including comparator and placebo, are manufactured;

(r) the favourable opinion of the Ethics Committee, and in case of parallel submission the updated version of documents or information as requested by the Ethics Committee;

(s) evidence of an appropriate quality management system or accreditation of the designated laboratory and a material transfer agreement; and

(t) any other documents and information as determined by the Agency.

(5) A clinical trial of an investigational product on humans shall only be commenced by a person in accordance with section 39 of the Act after the Ethics Committee has issued a written favourable opinion and the Agency

has approved the investigation based on the conclusion that the anticipated therapeutic and public health benefits justify the risks and shall only be continued if it is in compliance with the requirements observed throughout the trial.

(6) An application for a clinical trial may be made to the Ethics Committee and the Agency at the same time or sequentially.

(7) A clinical trial shall comply with the requirements of the Act and these Regulations.

(8) Where the clinical trial is sponsored by an individual, the applicant shall provide further information on-

(a) the availability of funds to conduct the trial;

(b) co-sponsoring by an institution recognised by the Agency where applicable; and

(c) any other conditions as determined by the Agency.

(9) The requirements provided under sub-regulation (4) shall apply in the case of an application for a clinical trial for a registered medicine, a registered indication or a registered dosage regimen for a registered medicine or substance.

(10) A person shall make an application for authorisation to the Agency with the prescribed form and fee -

(a) to amend the protocol of a clinical trial on behalf of a sponsor; and

(b) shall inform the Agency within seventy-two hours of any urgent amendments to be conducted to protect the life of the participants.

(11) The clinical trial of any investigational product may only be conducted on humans where-

(a) the foreseeable risks and inconveniences are medically justifiable when compared with the benefit on the participant, and the anticipated significance of the investigational medicinal product for the advance of medical science; and

(b) unjustifiable harmful effects on the health of a third person and the environment, are not to be expected if the clinical

trial consist of genetically modified organism, a combination of genetically modified organisms, contains any other organisms;

(c) in accordance with section 42 of the Act, the trial subject -

(i) is an adult and has been informed in a language that he or she understands, of the nature, significance and implications of the clinical trial,

(ii) has provided voluntary written informed consent with a signature or a thumb-print on the consent form,

(iii) is a minor or an incapacitated person, and his or her parents or legal guardians have been informed of the nature, significance and implications of the clinical trial and have provided a written voluntary informed consent and assent,

(iv) is informed of his or her right to withdraw from the clinical trial at any time,

(v) is provided with an information sheet with the risks associated to the clinical trials,

(vi) undergoes a counselling session with an investigator or a person designated by the investigator, and

(vii) is informed of the purpose and scope of the collection and use of personal data, especially medical data for the purposes of the trial.

(viii) is unable to read or write English, the informed consent shall be obtained in the presence of at least one impartial witness. The witness, who shall be able to read and write English and understand the local language in which the trial subject is informed, shall not be a member of the investigating team. The consent given by the trial subject shall be documented in writing, dated and signed by the witness and thumb printed or signed by the trial subject

(d) a declaration of consent to participate in a clinical trial, may be revoked orally or in writing at any time without prejudice to the trial subject, and the data collected and stored data may continue to be used where necessary;

(e) the trial is conducted in a high-quality facility by a qualified principal investigator in a professional manner who possesses the required educational and professional experience to be determined by the Agency to conduct a clinical trial;

(f) insurance coverage is provided for the trial subject in the event of an injury or death related to the clinical trial;

(g) advantages are not granted to the trial subject with the exception of adequate compensation;

(h) a medical doctor is responsible for the enrolment and medical care of the trial subject.

(12) In a public health emergency, the Agency may -

(a) expedite the application and review process for clinical trials; and

(b) make exemptions for the documents required to be submitted to the Agency for clinical trial applications.

(13) All clinical trials shall comply with the requirements for clinical trials provided under the Act and these Regulations and any exemptions shall be justified by the applicant and subject to approval by the Agency.

74. Special Pre-Conditions for Clinical Trials

(1) Where a clinical trial is to be conducted on an adult who suffers from a disease, to be treated by the investigational medicinal product, the use of the investigational medicinal product shall -

(a) be indicated according to the findings of medical science to save the life of the person, restore health and alleviate suffering; and

(b) be of direct benefit to a group of patients who are suffering from the same disease as the trial subject.

(2) In an emergency where consent cannot be obtained and treatment is required without delay to save the life of the trial subject, restore good health or alleviate suffering, the treatment may be commenced and consent shall be obtained for continued participation.

(3) Where a clinical trial is to be conducted on a minor who suffers or may suffer from a disease, to be treated by the investigational medicinal product the -

(a) use of the investigational medicinal product shall be indicated according to the findings of medical science to save the life of the person, restore health, alleviate suffering, and prevent disease;

(b) clinical trial shall be of direct benefit to a group of patients suffering from the same disease as the trial subject;

(c) research shall be considered necessary in order to confirm data obtained in clinical trials on other persons or by means of other research methods;

(d) research shall relate to a clinical condition from which the minor concerned is suffering or may suffer; and

(e) research may cause only a minimal risk and minimal burden to the trial subject.

(4) Where a clinical trial is to be conducted on an adult who is incapable of comprehending the nature, significance and implications of the clinical trial and suffers or may suffer from a disease, to be treated by the investigational medicinal product the-

(a) use of the investigational medicinal product shall be indicated, according to the findings of medical science to save the life of the trial subject, restore health and alleviate suffering;

(b) research shall relate directly to a life-threatening or highly debilitating clinical condition suffered by the trial subject;

(c) degree of burden and the risk threshold shall be defined specifically in the trial protocol and monitored constantly by the investigator;

(d) clinical trial may only be conducted if there is a justified expectation that the benefits of the investigational medicinal product for the trial subject outweigh the risks;

(e) consent by the authorised representative may be provided after he or she has been duly informed; and

(f) research shall be absolutely necessary for the confirmation of data obtained from clinical trials conducted on persons capable of granting informed consent or by means of other research methods.

75. Investigational Medicinal Products

(1) A person who intends to manufacture or supply investigational medicinal products for clinical trials shall ensure that it is carried out in accordance with internationally accepted good manufacturing practice principles.

(2) Investigational medicinal products for clinical trials shall be properly labelled as determined by the Agency.

(3) The Agency may –

(a) request for additional information;

(b) inspect a clinical trial;

(c) suspend or stop a clinical trial in accordance with section 44 of the Act; or

(d) withdraw the authorisation to conduct a clinical trial if-

(i) the safety of the trial subject is compromised,

(ii) the scientific reasons for conducting the trial has changed, or

(iii) the integrity of the data is compromised.

(4) An application may be made to the Agency in the prescribed form for a permit to import investigational medicinal products and shall include the-

(a) name, address and contact details of the sponsor of the clinical trial;

(b) name, address and contact details of the principal investigator;

(c) title and identification number of the clinical trial;

(d) planned clinical trial sites and the planned number of trial subjects at the sites;

(e) description of the investigational medicinal product with the name, code, strength and dosage form;

(f) unit of issue, total quantity, batch number or the equivalent as determined by the Agency;

(g) expiry dates of the products;

(h) sample of the labels of the primary and secondary packaging;

(i) certificate of analysis for the batch of investigational medicinal products;

(j) batch release certificate for biologicals;

(k) record of unused investigational medicinal products to be returned to the sponsor; and

(l) record of investigational medicinal products to be destroyed at the clinical trial site with the name and address of manufacturer.

(5) An authorisation for importation of an investigational medicinal product may be granted -

(a) after the approval of the study protocol by the Agency; or

(b) in exceptional cases to be determined by the Agency.

76. Disposal of Investigational Medicinal Products

(1) The disposal of investigational medicinal products shall be recorded and conducted in a professional manner by the principal investigator or sponsor representative.

(2) The record of disposal shall clearly identify the batch for disposal, the subject numbers and the quantities to be destroyed.

77. Procedures for Authorisation by the Agency and Favourable Opinion from the Ethics Committee

(1) An application for a favourable opinion may be made by the principal investigator to the Ethics Committee in the prescribed form in accordance with Regulation 73.

(2) The principal Investigator shall submit any other information as determined by the Ethics Committee to assess the application.

(3) The Ethics Committee-

(a) may rely on its personal scientific findings, consult experts or request for an expert opinion to assess any application;

(b) shall provide its opinion on an application for a clinical trial based on its written standard operating procedures;

(c) may refuse to grant a favourable opinion where the-

(i) documents submitted are incomplete and the principal investigator fails to submit the appropriate documents within the time frame provided by the Ethics Committee,

(ii) documents submitted, including the trial protocol, the investigator's brochure, the modalities for selection of trial subjects and the informed consent form, do not correspond with the scientific knowledge available and the clinical trial is considered unsuitable to provide proof of the safety and efficacy of a medicinal product, or

(iii) requirements specified under regulation 73 are not fulfilled.

(4) An application for the authorisation by the Agency in accordance with section 39 of the Act and regulation 73, shall be made by the principal investigator or sponsor to the Agency.

(5) An Authorisation may be refused in accordance with section 40 of the Act where the-

(a) documents submitted are incomplete and the principal investigator or sponsor fails to submit the appropriate documents within the time frame provided by the Agency;

(b) documents submitted, including data on the investigational medicinal products, the trial protocol, investigator's brochure and the investigational medicinal product dossier, do not correspond with the scientific knowledge available and the clinical trial is considered unsuitable to provide proof of the safety and efficacy of a medicinal product;

(c) in the case of clinical trials on humans the requirements stipulated under regulation 73, are not fulfilled; and

(d) Agency is in possession of findings which indicate that the clinical trial facility is not a conducive environment for the trial to be conducted.

(6) The Agency shall provide the Ethics Committee with any information of significance for the assessment of any application for a favourable opinion and shall include information on aborted or prematurely discontinued investigations.

(7) The Agency shall keep confidential any business and company secrets uncovered during the investigation.

(8) The Agency may use relevant clinical trial decisions, reports or information from other regulatory authorities as the Agency may consider necessary to assess any application.

(9) The Board may establish advisory committees in accordance with section 7 of the Act, as it may consider necessary for the review of clinical trial applications and for post-approval safety and compliance matters.

(10) All clinical trials shall be registered by the sponsor or principal investigator in a public international database as determined by the Agency for easy access.

78. Revocation and Suspension of the Authorisation

(1) The Agency shall revoke an authorisation where it becomes aware –

(a) of the applicant`s non-compliance with one of the requirements under Regulation 73 at the time the authorization was issued;

(b) that one of the requirements for withdrawal is fulfilled under regulation 75; or

(c) that the conditions surrounding the clinical trial do not correspond with the information contained in the authorisation application or if facts give reason to doubt the safety or the scientific basis of the clinical trial.

(2) The Agency may in accordance with section 44 (1) of the Act and these Regulations or for any reasonable cause suspend an authorization and shall notify the holder of its decision and the reasons for the decision.

(3) A person aggrieved by a decision of the Agency may make a representation within seven days to the Agency.

(4) Where a representation is not made to the Agency within seven days, the decision of the Agency shall be final.

(5) The suspension or revocation of an authorisation shall not apply retrospectively.

(6) Where the authorisation to conduct a clinical trial is revoked or suspended, the clinical trial shall not be continued.

(7) The Agency shall immediately notify the Ethics Committee of its decision to suspend or revoke an authorization with the grounds for its decision.

(8) The Ethics Committee may withdraw a favourable opinion where it becomes aware that the grounds for refusal in accordance with regulation 77 (5) existed at the time the opinion was granted and the-

(a) requirements regarding the suitability of the investigator, the deputy or the trial site are no longer fulfilled;

(b) clinical trial participants are not provided with insurance coverage or the prerequisites for an exception to the insurance obligation does not exist;

(c) modalities for selecting trial subjects no longer correspond to the current state of medical knowledge;

(d) clinical trial is unsuitable for providing proof of the safety or the efficacy of the investigational medicinal product; and

(e) prerequisites for the inclusion of persons in accordance with regulation 73 and 74 are no longer fulfilled.

(9) The Ethics Committee shall notify the Agency of its decision to withdraw an opinion with the grounds for its decision.

(10) Where the Agency becomes aware that a person no longer fulfills his or her obligations in accordance with to the proper conduct of the clinical trial the Agency shall order the person conducting the clinical trial to stop or suspend the trial immediately.

(11) Regulatory sanctions may include-

(a) a caution statement;

(b) imposition of timeline to address any deviation; and

(c) the rejection of the trial data.

79. Inspection of Clinical Trials

The Agency shall inspect a clinical trial to ensure -

(a) adequate protection of the general public is provided against the risks or adverse effects from the clinical trial of a medicine; and

(b) that the trial is conducted in accordance with the Act and the specific and general conditions of these Regulations.

80. Notification of Adverse Events and Clinical Trial Reports

The principal Investigator shall-

(a) report any serious adverse events suspected to be related to the investigational product to the Agency and the Ethics Committee within fifteen calendar days;

(b) report all deaths whether related or not to the investigational product within seventy two hours;

(c) inform the Agency of any adverse events as part of the end of study report;

(d) submit to the Agency all safety update reports;

(e) submit progress reports to the Agency; and

(f) the final clinical trial summary report within a time frame to be determined by the Agency.

PART XII - DISPOSAL OF MEDICINES AND RELATED PRODUCTS

81. Disposal of Medicines and Related Products

(1) A medicine or related product shall only be destroyed upon application, approval and supervision by the Agency, including investigational products used in clinical trials.

(2) The disposal of a medicine and related product shall be conducted in a manner to be determined by the Agency to ensure that the medicine and related product is incapable of being salvaged and is denatured where necessary.

(3) All medicines and related products shall be destroyed in the presence of an Inspector of the Agency or any other person authorised by the Executive Director of the Agency.

(4) The advice and support of the National Environmental Agency may be solicited by the Agency for the disposal of medicines and related products.

PART XIII - INTERNATIONAL COOPERATION AND HARMONISATION OF REGULATION OF MEDICINES AND RELATED PRODUCTS

82. International Cooperation

(1) The Agency may -

(a) cooperate with other national, regional and international organisations and medicines and related products regulatory agencies;

(b) share pharmaceutical intelligence on products that pose public health risks with other organisations and medicines regulatory agencies at the regional, continental and global level;

(c) take appropriate measures to ensure effective bilateral, regional and international co-operation to combat the production, circulation and use of substandard and falsified medicines and related products, illicit drugs, narcotics and psychotropic substances;

(d) participate in regional and international harmonisation initiatives; and

(e) establish networks, share information and conduct joint regulatory activities with other regulatory bodies and relevant international organisations.

(2) The principles of reliance and mutual recognition may be used to support and inform the decision-making process of regulatory activities of the Agency.

83. Regulatory Harmonisation Initiatives

The Agency may take such measures as it considers necessary to ensure effective co-operation with other Authorities or Organisations to-

(a) harmonise the registration of medicine and related products, inspections, quality management systems, information management systems, joint evaluations, joint inspections and any other regulatory activities as may be appropriate;

(b) provide for the use of accredited quality control laboratories within the harmonisation framework;

(c) provide for the recognition of regional, continental and other international technical guidelines;

(d) provide for cooperation and establish exchange programmes with other organisations or regulatory agencies for the purpose of strengthening national regulatory capacity; and

(e) provide for transparency and information sharing through the-

(i) establishment of a quality management system, and

(ii) creation of an information management system which allows for the sharing of information at regional and international levels in accordance with national laws, bilateral and multilateral agreements.

PART XIV - MONITORING AND EVALUATION

84. Monitoring and Evaluation

(1) The Agency shall create a monitoring and evaluation system tasked with reviewing and assessing the performance of the Agency.

(2) The Agency shall prepare periodic reports to be presented to the Board of the Agency.

(3) The Agency shall prepare annual reports on the performance of the Agency to the Minister.

PART XV - MISCELLANEOUS PROVISIONS

85. Standards

(1) All medicines and related products shall conform to the prescribed standards as determined by the Agency.

(2) All medicines shall conform to the pharmacopoeia standards accepted by the Agency and shall include the-

(a) British Pharmacopeia;

(b) the British Pharmacopeia Codex;
(c) International Pharmacopeia;

(d) European Pharmacopeia;

(e) United States Pharmacopeia; and

(f) any other standards recognised by the Agency.

(3) All related products that are described as conforming to particular descriptions shall conform to those descriptions as determined by the Agency.

86. Declaration and Conflict of Interest

(1) A staff of the Agency, member of the Board or of a Committee appointed by the Board shall declare any interests related to any medicine or related product, which may be relevant to any decision-making.

(2) A person who has an interest in a matter for consideration shall disclose the nature of that issue in writing and is disqualified from

participating in any deliberations in respect to any decision-making on that matter.

87. Restriction of Liability

(1) The Agency, the Board, a Committee member or a staff of the Agency shall not be liable for any loss or damage arising from any decision made or act carried out in good faith in the exercise of powers or performance of functions under the Act and these Regulations.

(2) The Agency, the Board, a committee member or a staff of the Agency shall be liable for any loss or damage if the loss or damage is due to willful misconduct, gross negligence or failure to comply with the Act and these Regulations.

88. Protection of and access to information

(1) A person shall not disclose to any person, any confidential information acquired in the exercise of his or her powers or in the performance of his or her functions under the Act and these Regulations.

(2) A person may be permitted to disclose information -

(a) for the performance of his functions under the Act and these Regulations with the written authority of the Agency;

(b) when required to do so by any competent court or under any law; or

(c) in the public interest to be determined by the Agency.

89. Fees and Fines

(1) The Agency shall introduce or review administrative fees which shall be published in the gazette as it deems necessary.

(2) Administrative fees and fines imposed and other revenue recovered by the Agency in the enforcement and implementation of these Regulations shall be maintained by the Agency.

90. Repeal

The Medicines Regulations1986 are hereby repealed.

SCHDULES

SCHEDULE 1

OVER THE COUNTER (OTC) MEDICINES (INCLUDING NUTRITIONAL SUPPLEMENTS)

This Schedule does not include any parenteral preparation

1. Antipyretic, Analgesic
   Paracetamol (Acetaminophen) except suppositories
2. Non-Steroidal Anti-inflammatory Drugs (NSAIDs)
   Ibuprofen (200mg, 400mg), Acetylsalicylic acid, Diclofenac (25mg) and topical preparations
3. Analgesic combination
   Paracetamol and Ibuprofen (200mg, 400mg)
4. Antihistamines and Antiemetics
   Topical preparations
5. Antacids,
   Algicon and its analogues, Magnesium, Aluminium, Sodium, Calcium, Simethicone and Bismuth containing antacids, Milk of Magnesia
6. Antidiarrhoeals
   Oral Rehydration Salts (ORS), Loperamide, Kaolin and Pectin containing compounds
7. Antiseptics, disinfectants and cleansing agents for topical applications
   Cetrimide, Chlorhexidine, Glutaraldehyde, Magnesium sulphate powder, Phenol (Lysol)
8. Wound disinfectants for topical applications
   Gentian violet (Crystal violet) paint, Hydrogen peroxide, Povidone Iodine, Iodine Mercurochrome
9. Antiscabies and Warts preparations
   Benzyl benzoate, Podophyllin, Silver nitrate
10. Antimalarials
    Artemether + Lumefantrine, Sulphadoxine + Pyrimethamine 500mg/25mg, Amodiaquine + Artesunate, Artesunate suppository, Artemether suppository, Dihydroartemisinin suppository, Dihydroartemisinin + Piperaquine tabs,
11. Antihelminthics
    Albendazole, Mebendazole,
12. Antihaemorrhoids
    Topical preparations

13. Cold preparations including nasal decongestants containing Ephedrine
14. Cough preparations except those containing Morphine and its analogues (e.g. Codeine)
15. Laxatives
    Liquid paraffin, Glycerin, Castor oil, Senna Tablets, Senna liquid
16. Contraceptive foaming tablets
17. Contraceptives (low dose containing not more than 35 mcg Oestrogen or Progestrogen)
    Norgestrel 30mcg+ Ethinylestradiol 30mcg,
    Levonorgestrol 30mcg tabs
    Levonorgestrol 150mcg + Ethinylestradiol 30mcg tabs
    Cyproterone acetate 2mg + Ethinylestradiol 35mcg tabs
18. Glucose (Dextrose) powder
19. Emollients and protectives
20. Aural preparations
    Olive oil
21. Topical counter irritants
    Crotamiton, Calamine lotion
22. Topical antifungals
    Nystatin, Benzoic acid/Salicylic compound, Clotrimazole preparations, Miconazole, Ketoconazole shampoo
23. Topical acne & pimples preparations
    Benzoyl peroxide, Salicylic acid, Sulphur, Almond oil
24. Ophthalmic preparations
    Tetracycline, Chloramphenicol, Eye wash solutions
25. Topical antibiotics
    Tetracycline, Gentamycin, Neomycin & Bacitricin, Silver sulphadiazine
26. Oral Antibiotics
    Cotrimoxazole (Sulphamethozaxole + Trimethoprim) preparations only
27. Oral Vitamins and Minerals preparations
28. Oral Antianaemics
    Ferric and Ferrous salts and their combinations, Folic acid, Vitamin B12, Blood tonics
29. Antidotes
    Activated charcoal
30. Nutritional Supplements preparations
31. Water for injection

SCHEDULE 2

P

PHARMACY MEDICINES

The following are medicines that do not require a medical practitioner's prescription but may only be supplied on the recommendation of a pharmacist on professional judgment and who shall maintain proper records.

The salts, preparations and admixtures of the following-

Acetarsol
Acetic acid syrup
Acetylcysteine oral
Aconite
Acyclovir (not more than 5%)
Adapalene cream
Aescin, preparations intended for topical use only
Alfacalcidol
Alimezanine (trimeprazine), Alkali fluorides other than dentrifices containing not more than 0.3% of the alkali salts of hydrofluoric acid
Aloxiprin
Ambroxol + clenbuterol
Amino-alcohols, esterified with benzoic acid, phenylacetic acid, phenylpropionic acid, cinnamic acid, or the derivatives of these acids, their salts, being preparations for oral use only
Aminopentamidine
Aminophylline, other than parenteral preparations
Ammonia
Amodiaquine
Amoxycillin, other than parenteral preparations
Amphotericin lozenges
Ampicillin, other than parenteral preparations
Amyl nitrate
Anaesthetic agents intended for topical use and procaine for oral use
Antazolin
Anthraquinone
Antibacterial eye preparations for use in Trachoma
a. eye ointments containing one per cent Tetracycline, or
b. Oxytetracycline
Antifungal preparations for vaginal use and topical preparations (excluding Whitfields, Undecylenic acid)

Antihistaminic substances, the following :–
Antazoline;
Bromazine;
Buclizine;

Carbinoxamine
Chlorcyclizine
Clemastine
Clemizole
Cyanocobalamine in oral combinations
Cyclizine
Cyproheptadine
a. liquid preparations containing 5mg or less per unit dose alone or in combinations with other active ingredients
b. preparations in solid dosage forms containing 15mg or less per unit dose in combinations with other active ingredients
Dexchlorpheniramine
Dephenylpyraline
Phenindamine
Pheniramine
Phenylephrine, other than preparations containing less than 0.2% phenylephrine intended for topical use
Pholcodine, in the form of liquid preparations only
Tolpropamine
Tripolidine
Astemizole
Barium
Beclomethasone inhaler (for use in asthma)
Belladonna, and the alkaloids thereof
Bendrofluazide (not more than 5mg)
Benzidamide
Benzoyl peroxide
Bisacodyl
Bismuth subgallate and its combinations
Bitolterol mesylate
Bromazine
Bromelains
Bromhexine
Buclizine
Calciferol
Calcium salts
Camylofin
Caramiphen
Carbinoxamine
Carbocisteine
Carbuterol
Cetirizine tablets and syrup
Chloral, all salts and derivatives
Chlorbenoxamine
Chlorbutol, except when intended for use as a preservative
Chlorcyclizine

Chlormezanone, preparation containing 100mg or less in combination with analgesic or anti-asthmatic drug
Chlorphenesin
Chlorpheniramine
Choline theophyllinate
Chrysarobin
Cimetidine (not more than 200mg)
Ciprofloxacin (for treatment of Sexually Transmitted Infections only)
Clobutinol
Codeine
a. Containing 5mg or less per unit dose alone or in combinations with other active ingredients in solid dosage forms
b. Containing 15 mg or less per unit dose in combination with other active ingredients in liquid dosage forms
Corticosteriods; topical preparations containing 1% or less
Creosate, obtained from wood, other than substances containing less than 50% Creosote
Cyclandelate
Cyclopentolate
Diclofenamide
Dequalinium
Dextromethorphan
Desloratidine
Dextran + Hydroxypropylcellulose eye drops
Dibromopropamidine
Dicycloverine (Dycyclomine)
Diclofenac 50mg & 75mg Tablets, capsules and suppositories
Diethylamine salicylate
Diloxanide
Dimethindene
Diphenhydramine
Diphenoxylate, preparations containing 2.5mg or less per unit dose in combination with other active ingredients
Dithranol (not more than 5%)
Docusate eye drops
Domiphene bromide
Domperidone
Doxycycline (for treatment of Sexually Transmitted Infections only)
Doxylamine
Erythromycin (for treatment of Sexually Transmitted Infections only)
Etafedrine
Ethynitrate
Formaldehyde, other than when used as a preservative
Furazolidone
Fedrilate
Fenbufen
Fenoprofen

Fenoterol
Floctafenine
Fluconazole
Flucloxacillin, other than the parenteral preparations
Flurbiprofen
Furazolidine
Gamma benzene hexachloride
Glucuronic acid
Glyceryl trinitrate
Griseofulvin
Halquin (Chlorhydroxyquinoline) (Di-iodohydroxyquinoline)
Hexachlorophene, preparations containing more than 1 per cent hexachlorophene
Hexitidine
Hexoprenaline
Hormones, all oral contraceptives and vaginal preparations except low dose contraceptives
Hyaluronidase
Hydrochloric acid, as diluted solution for achlorhydria
Hydrocortisone, preparations intended for external use containing 1% or less hydrocortisone
Hydroaltacite
Hyoscyamine
Hyoscine
Ichthammol
Indomethacin
Iodine, Iodides
Isoaminile
Isothipendyl
Ivermectin
Lactulose (for constipation only)
Levallorphan
Levamisole
Levonorgestrel
Lignocaine and its combinations (topical preparations)
Loratidine syrup and tablets
Methenamine (Hexamine)
Mebhydrolin
Meclozine
Mefenamic acid
Metoclopramide (oral preparations)
Methocarbamol
Methoxyphenamine
Metronidazole, other than parenteral preparations
Morphine, only in the form of Gee's Linctus and Tinct. Camph. Co
Mytecaine
Nadifloxacin topical preparations

Naphazoline
Naproxen
Niclosamide
Nicotinic acid
Nonoxynol-9 pessaries
Norfloxacin + tinidazole
Noscapine
Nystatin, except pessaries and creams
Olopatadine eye drops
Omeprazole other than injection
Opium, only in the form of Gee's Linctus and Tinct, Camphor Co
Orciprenaline
Oxetacaine
Oxymetazoline
Oxyphencyclimine
Paracetamol + Diclofenac
Pancreatin
Pantothenic acid
Papaverine, substances containing less than 1% papaverine
Paracetamol (Acetaminophen) suppositories
Pentifyllin
Pentoxyverine
Phenazone
Pimecrolimus topical
Pholedrine
Pirbuterol
Poldine metisulfate
Potassium chloride
Pramoxine topical preparations
Praziquantel
Prednisole (management of skin conditions)
Prednisolone (management of skin conditions)
Procaterol
Proguanil
Promethazine
Propamidine
Propantheline bromide
Propylenediamine
Tetra substituted N derivatives of ethylenediamine or propylenediamine
Quinine (when used for nocturnal cramps)
Ranitidine other than injection
Rimiterol
Ritodrine
Salbutamol, including inhaler
Selenium
Sildenafil
Sodium aescinate for topical use

Sodium cromoglycate
Sucralfate
Sulfiram, preparations intended for topical use only
Sulphonamides other than those under POM
Terbutaline
Terpine hydrate
Tetanus toxoid
Tetracycline (for treatment of Sexually Transmitted Infections only)
Thenalidine
Theophylline
Tolazoline for topical use
Tolpropamine
Tribenoside
Tricyclamol chloride
Triprolidine
Vitamin A (Retinol) other than preparations containing 10 thousand units or less of Vitamin A activity per unit dose
Xylometazoline and analogues
Yohimbine containing products
Zinc oxide
Zinc sulphate
And any substances derived from any of the medicines referred to in this Schedule, unless expressly excluded.

SCHEDULE 3

POM

PRESCRIPTION ONLY MEDICINES

The salts, preparations and admixture of the following:

Acarbose
Acebutolol
Acetazolamide
Acetohexamide
Acetylcysteine parenteral & inhalation
Acetyldigitoxin
Acetyldihydrocodeine
Actinomycin-D
Acyclovir
Aescin, other than preparations intended for topical use only
Aceclofenac
Alcuronium
Alfadolonum
Alfaxalonum
Alfentanil
Alfuzosin
Allergy desensitization treatment sets, in graded doses
Allopurinol
Alprazolam, CD
Alprostadil
Alseroxylon
Altretamine
Amantadine
Amineptine
Aminocaproic acid
Aminophylline (parenteral preparations)
Amitriptyline
Amlodipine
Ampiclox
Ampicillin (parenteral preparations)
Amoxapine
Amphotericin (except in lozenges)
Anaesthetic agents, including local anaesthetics intended for injection, but excluding those preparations intended for topical use and procaine for oral use
Anastrozole
Antibacterial eye preparations other than the following-
a. eye ointments containing 1% Tetracycline or Oxytetracycline which are for use in Trachoma; and
b. Chloramphenicol eye preparations
Antimony
Antiretrovirals as per national HIV treatment programme

Arteether (beta alfa) injection
Artemether (parenteral preparations)
Artesunate (parenteral preparations)
Atenolol
Atracurium
Atropine
Azacyclonal
Azathioprine
Azapropazone
Azithromycin
Baclofen
Barbituric acid, other than preparations containing 15mg or less in combination with other medicines per unit dose
Bemagride
Benzathine penicillin (Penicillin G-Procaine)
Benztropine
Benzydamine
Benzylpenicillin (Penicillin G, Crystalline Penicillin)
Betahistine
Betamethasone
Betaxolol
Bicalutamide
Bimatoprost
Biologicals
Bisoprolol
Brimonidine
Brinzolamide
Bromazepam, CD
Bromocriptine
Bromvaletone
Brucine
Budesonide
Bumadizon
Bumetanide
Bupivacaine and its combinations
Buprenorphine
Buserelin
Busulfan
Cabergoline
Calcitonin
Calcium dobesilate
Calcium gluconate
Camylofin
Candesartan
Capecitabine
Captodiame
Captopril

Carbachol
Carbamazepine
Carbenicillin
Carbidopa
Carbimazole
Carisoprodol
Carvedilol
Cephalosporins (all generations)
Chlorambucil
Chloramphenicol other than eye preparations
Chlordiazepoxide, CD
Chlormethiazole
Chlorotrianisene
Chlorpromazine
Chlorpropamide
Chlorprothixene
Chlorthalidone
Chlortrianisene
Cimetidine containing more than 200mg
Cinnarizine
Ciprofloxacin only preparations
Ciprofloxacin + metronidazole preparations
Ciprofloxacin + tinidazole preparations
Cisplatin
Clarithromycin
Clavulanic Acid
Chlolestyramine
Clindamycin
Clioquinol (as 3% in topical preparations only)
Clobazam CD
Clobetasol propionate
Clobetasone butyrate
Clofazimine
Clofibrate
Clomiphene
Clomipramine
Clonazepam CD
Clonidine
Clopamide
Clopidrogel
Clorazepate
Clostridium botulinum toxin type A
Clotiapine
Cloxacillin
Clozapine
Coca alkaloids, CD
Codeine

a. other than liquid preparations containing 5mg or less per unit dose alone or in combinations with other active ingredients; and
b. other than preparations in solid dosage or containing 15 mg or less per unit dose in combination with other active ingredients
Colchicine
Conjugated oestrogens
Cortisone acetate for buccal use
Cromoglycic acid
Cyanocobalamine (except in oral combinations)
Cyclofenil
Cyclopenthiazide
Cyclophosphamide
Cyclosporin
Cyproterone
Cytarabine.
Dacarbazine
Dalteparin sodium
Danazol.
Dapsone and its combinations
Darunavir
Daunorubicin
Deanol
Debrisoquine
Demecarium bromide
Desferoxamine
Desipramine
Desmopressin acetate
Dexamethasone
Diazepam and other compounds containing the chemical structure of dihydro-1, 4-Benzodiazepine substituted to any degree, CD
Dibenzepin
Dichloralphenazone
Diclofenac 100mg Tablets, Capsules and suppositories
Diclofenamide
Didanosine
Diethylpropion
Diethylstilboestrol
Digitalis, digoxin and other cardiac glycosides
Dihydralazine
Dihydrocodeine
Dihydroergocristine
Diloxanide furoate
Diltiazem
Dimercaprol
Dimethotiazine
Dinoprost
Dinoprostone

Dioxyanthanol (Dithranol)
Diphenidol
Diphenoxylate, other than in preparations containing 2.5 mg or less per single unit dose
Dipotassium clorazepate
Dipyrone
Disopyramide
Disulfiram
Dobutamine
Domperidone
Dopamine
Dosulepin
Doxapram
Doxazosin
Doxepin
Doxorubicin
Doxycycline
Droperidol
Drotaverin
Duloxetine
Dyflos
Econazole
Efavirenz
Ethylurea
Edrophonium
Emetine, other than Tinct. Ipecacuanha
Emtricitabine + Tenofovir.
Emylcamate
Enalapril
Enoxaparin
Entecavir
Enzaprost F
Enzymes
Ephedrine
Epinastine
Eplerenone
Ergometrine
Ergotamine
Erythrithyl tetranitrate
Erythromycin
Erythropoietin
Esomeprazole
Etamsylate
Ethacrynic acid
Ethambutol
Ethambutol + Isoniazid + Pyrazinamide + Rifampicin
Ethambutol + Isoniazid + Rifampicin

Ethchlorvynol
Ethinamate
Ethionamide
Ethoheptazine
Ethylurea
Etomidate
Etonogestrel
Etoposide
Exemestane
Famciclovir
Famotidine
Felodipine
Fencamfamin
Fentanyl, CD
Fexofenadine
Filgrastrim
Finasteride
Flucloxacillin
Fluconazloe
Flucytosine
Fludrocortisone
Flumazenil
Flutemazepam, CD
Flunitrazepam, CD
Fluocinolone
Fluocinonide
Fluoromethalone
Fluorouracil
Fluoxetine
Fluphenazine
Flurazepam, CD
Fluticasone
Flutamide
Fluvastatin
Folinic Acid
Formoterol
Fosinopril
Framycetin, other than topical
Furosemide
Fusidic Acid
Gadopentetate dimeglumine
Gatifloxacin
Gelsemium
Gentamycin
Glafenine
Glibenclamide
Gliburide

Glimeperide
Glucose (Dextrose) and its combinations (parenteral preparations)
Glutamic acid
Goserelin
Guanethidine
Halofantrine
Haloperidol
Halothane
Heparin
Hexamethonium bromide
Hexetidine
Homatropine
Hormones, natural or synthetic preparations intended for systemic effect other than
a) ampoules of Adrenaline (Epinephrine) (one part of adrenaline in ten thousand parts of solvent) used in the treatment of snakebite or use in emergency (1mg/ml);
b) progestational and oestrogenic substances used for the control of ovulation in the human
Human chorionic gonadotrophin
Hydralazine
Hydrochlorothiazide
Hydrocortisone, other than in topical preparations containing 1% or less
Hydroquinone, other than preparations intended for external use containing 2% or less
Hydroxyprogesterone
Hydroxyzine
Ibandronic acid
Ibuprofen tablets which are 600mg and above
Idoxuridine
Imipramine
Indapamide
Indoprofen
Infliximab
Insulin
Ipratropium
Iron preparations intended for injection
Isoetarine
Isoflurane
Isoniazid
Isoniazid + Rifampicin
Isoniazid + Rifampicin + Ethambutol
Isoniazid + Thiacetazone
Isosorbide dinitrate
Isradipine
Itraconazole
Ketamine

Ketazolam
Ketoconazole
Ketoprofen
Ketorolac
Ketotifen
Labetalol
Lactulose (for liver cirrhosis)
Lamivudine
Lanatoside
Latanoprost
Leucovorin and its combinations
Levobunolol
Levodopa
Levofloxacin
Lidoflazine
Lignocaine and its combinations (parenteral preparations)
Lincomycin
Lisinopril
Lithium and its salts
Lopinavir + Ritonavir
Lorazepam, CD
Lormetazepam
Losartan
Loxapine
Ludexium
Magnesium sulphate (parenteral preparations)
Mannitol (parenteral preparations)
Maprotiline
Mazindol
Mecobalamine
Medazepam, CD
Medroxyprogesterone
Melarsoprol
Mefloquine
Meglumine
Melphalan
Mephenesin
Mephenoxalone
Mephenytoin
Mepivacine
Meprobamate
Mercaptopurine
Meropenem
Mercury, other than solutions of mercurochrome for topical application containing less than 3%
Mesna
Mesuximide

Mesterolone
Metaraminol
Metformin
Methadone, CD
Methohexitone
Methyldopa
Methyl phenidate, CD
Methysergide
Metoclopamide (parenteral preparations)
Metoprolol
Metrifonate
Metronidazole (parenteral preparation)
Mexiletine
Mianserin
Midazolam, CD
Mifepristone
Mifepristone + Misoprostol
Milrinone lactate
Minocycline
Minoxidil
Misoprostol
Mitoxantrone
Molindone
Mometasone
Monoamine oxidase inhibitors
Morphine, other than in the form of Gee's Linctus and Tinct. Camphor. Co., CD
Moxifloxacin
Mupirocin
Nadolol
Nadropine
Nalidixic Acid
Nalorphine CD
Naloxone
Natamycin
Nelfinavir
Neomycin
Neostigmine
Nevirapine
Nifedipine
Niflumic Acid
Nimesulide
Nimorazole
Niridazole
Nitazoxanide
Nitrazepam, CD
Nitrofurantoin

Nitroxoline
Nomifensine
Norethisterone
Norfloxacin
Nux vomica
Oestradiol, in oestrogen deficiency states and menopause
Ofloxacin
Olanzapine
Omeprazole injection
Opium, other than in the form of Gee's Linctus, Camphor Co., CD
Orlistat
Ornidazole
Orphenadrine
Oseltamivir
Oxamniquine
Oxazepam, CD
Oxalinic acid
Oxprenolol
Oxybutyrin
Oxygen (medical grade)
Oxyphenisatin.
Oxytetracycline
Oxytocin
Pancuronium
Pantoprazole
Parecoxib
Pargyline
PEG-Interferon alfa-2A
Penbutolol
Penicillins
Pentaerythritol tetranitrate
Pentamidine
Pentazocine, CD
Pentolinium tartrate
Perfloxacin
Perhexiline
Pethidine, CD
Phecacaine
Phenacetamide
Phenaglycodol
Phenindione
Phenobarbital, CD
Phenobarbitone, CD
Phenothiazine other than –
a. Anthelmintics
b. Dimethoxanate in anti-tussive preparations containing 2.5 mg or less per unit dose

Phenoxymethyl penicillin (Penicillin V)
Phensuximide
Phentermine, CD
Phenytoin
Physostigmine
Picrotoxin
Pilocarpine
Pimozide
Pinazepam, CD
Pioglitazone
Piperacillin + Tazobactam
Piracetam
Pituitary Gland hormones and the active principles thereof, except when intended for topical applications and in inhalants.
Piroxicam capsules
Pizotifen
Plasma expanders
Podophyllum resin
Practolol
Pranoprofen
Pravastatin
Prazepam CD
Prazosin
Pregabalin
Procarbazine
Prednisole (other than for skin conditions)
Prednisolone (other than for skin conditions)
Prenylamine
Preparations containing corticosteroids for intra or peri-anal use
Primidone
Probenicid
Procainamide
Procaine hydrochloride
Procaine penicillin
Prochlorperazine
Procyclidine
Prolintane
Promethazine (parenteral preparations)
Propofol
Propoxyphene, including dextro-propoxyphene and its salts and preparations
Propranolol
Propylhexidrine
Propylthiouracil
Protamine sulphate
Prothipendyl
Protryptiline

Proxymetacaine
Pyrazinamide
Pyrazinamide + Isoniazid + Rifampicin preparations
Pyrimethamine
Pyritinol
Quinapril + Hydrochlorthiazide
Quinethazone
Quinidine
Quinine
Rabies Immunoglobulins
Raltegravir
Ramipril
Ranitidine injection
Reserpine
Ribavirine
Rifampicin
Risperidone
Rituximab
Rofecoxib
Rosuvastatin
Rosiglitazone
Rosoxacin
Roxithromycin
Salbutamol (parenteral preparations)
Salmeterol
Secnidazole
Sertaconazole
Setraline
Sibutramine
Simvastatin
Snake venom antiserum
Sodium bicarbonate
Sodium calcium edetate
Sodium chloride
Sodium fluoride, excluding dental preparations
Sodium lactate
Sodium pentosan polysulphate
Sodium valproate
Somatropine
Sotalol
Sparfloxacin
Spectinomycin.
Spironolactone
Stilboestrol
Streptokinase, streptodornase, and other enzymes obtained from microbiological cultures
Streptomycin

Styramate
Sulfiram, other than for topical use
Sulphinpyrazone
Sulphonal
Sulphonamides, including combinations with other active ingredients, other than for intra-vaginal, ophthalmic and topical use, and for use in malaria treatment.
Sulpiride
Sulthiame
Suxamethonium
Syrosingopine
Tageserod
Tamoxifen
Telbivudine
Temazepam, CD
Temozolomide
Tenoxicam
Tetracycline
Tetrabenazine
Theophylline Anhydrous (except in preparations containing 120mg or less)
Thiacetazone
Thiamphenicol
Thioguanine
Thiopentone
Thioridazine
Thiothizene
Thymoxamine hydrochloride
Thyroid gland hormones, natural and synthetic derivatives but excluding radioactive derivatives
Thyroxine
Tiaprofenic acid
Timolol
Tinidazole
Tizanidine
Tobramycin
Tolazamide
Tolbutamide
Tolfenamic acid
Tolmetin
Tramadol, CD
Tranexamic acid
Tranylcypromine
Tretinoin
Triamcinolone
Triazolam, CD
Tribromomethyl alcohol
Trichlorethyl alcohol

Trichloracetic acid
Trifluoperazine
Trifluperidol
Trihexyphenidyl (Benzhexol)
Trimepramine
Trimethadion
Trimethaphan
Trimethoprim
Tropicamide
Vaccines, Sera and Antigens
Valaciclovir
Valdenafil
Valproic acid
Valsartan
Vancomycin
Vasopressin
Verapamil
Veratrum
Viloxazine
Vinblastine
Vincristine
Vindesine
Vitamin A (Retinol) (preparations containing more than 10 thousand units of Vitamin A activity per unit dose)
Vitamin B (compound) (parenteral preparations)
Vitamin K (Phytomenadione) and its analogues other than supplements
Voriconazole
Xamoterol
Zafirlukast
Zolmitriptan
Zolpidem, CD
Zopiclone, CD

And any substances derived from any of the medicines referred to in this Schedule, unless expressly excluded.

CD – refers to drugs controlled under the United Nations Conventions of 1961, 1971 and 1988.

SCHEDULE 4

HERBAL MEDICINES

This Schedule includes all herbal medicines listed in the WHO Monographs on Selected Medicinal Plants, WAHO Herbal Pharmacopoeia, European Medicines Agency Committee on Herbal Medicinal Products (HMPC) Monographs and The Gambia list of herbal products as published by Traditional Medicines Programme.

SCHEDULE 5

VETERINARY MEDICINES

The salts, preparations and admixture of the following:
Acepromazine
Acriflavin
Afoxolaner
Aglepriston
Activated charcoal
Albendazole
Allantoin
Altrenogest
Aluminium salicylate
Aluminium silicate
Aminoacridin
2-Aminoethyl-dihydrogen-phosphate
Aminonitrothiazol
Amitraz
Amlodipine
Ammonium chloride
Amoxicillin
Ampicillin
Ascorbic acid
Atipamezol
Azaperon
Bacitracin
Benazepril
Benzalkoniumchlorid
Benzethoniumchlorid
Benzoic acid
Benzyl benzoate
Benzylpenicillin
Betamethasone

Bismuth aluminate
Bismuth subnitrate
Bromhexine
Brotizolam CD
Buprenorphine CD
Buserelin
Butafosfan
Butorphanol
Butylscopolamine
Cabergoline
Calcium borogluconate
Calcium carbonate
Calcium chloride
Calcium gluconate
Calcium hydroxide
Calcium phosphate
Campher
Carbetocin
Carbimazol
Carprofen
Cefalexin
Cefapirin
Cefoperazon
Cefovecin
Cefquinom
Ceftiofur
Chloramin T
Chloramphenicol
Chlorhexidine
Chlorphenamin
Chlortetracyclin
Cholecalciferol
Chondroitinsulfat
Cimetidine
Cimicoxib
Clavulanic acid
Clenbuterol
Clindamycin
Clomipramine
Cloprostenol
Clorsulon
Closantel
Clotrimazole
Cloxacillin
Codeine CD
Colistin
Copper sulfate

Copper-(II)-chloride
Coumafos
Cropropamide
Crotethamide
Cyanocobalamin
Cyclosporin
Danofloxacin
Deltamethrin
Dembrexin
Deslorelin
Desoxycortone
Detomidin
Dexamethasone
Dexmedetomidine
Dichlorophen
Diclazuril
Difloxacin
Diflubenzuron
Dihydrostreptomycin
Dimethylsulfoxid
Dimeticon
Dimpylat
Dinotefuran
Diphenhydramine
Doramectin
Doxycycline
Embutramid
Emodepside
Enilconazol
Enrofloxacin
Ephedrine
Eprinomectin
Epsiprantel
Estriol
Ethacridin
Etiproston
Eucalyptol
Febantel
Fenbendazol
Fenpipramid
Ferrum oxydatum saccharatum
Fipronil
Firocoxib
Florfenicol
Flubendazol
Flumethrin
Flunixin

Fluoxetine
Fluralaner
Formaldehyde
Formic acid
Framycetin
Fructose
Furosemide
Fusidic acid
Gamithromycin
Gentamycin
Gleptoferron
Glucose
Glycerol
Gonadotropin-releasing factor
Grapiprant
Guajacol
Halofuginone
Hyaluronic acid
Hydrocortisone
Hydroxyzine
Imepitoin
Imidacloprid
Imidapril
Imidocarb
Indoxacarb
Insulin
Interferon Omega
Iodine
Iron-(III)-oxide
Iron dextran
Isoflurane
Isopropyl alcohol
Isoxsuprin
Itraconazole
Ivermectin
Kanamycin
Kaolin
Ketamine
Ketanserin
Ketoprofen
Lecirelin
Levamisole
Levomethadone CD
Levothyroxin
Lidocain
Lincomycin
Locatim

Lokivetmab
Lotilaner
Lufenuron
Luprostiol
Magnesium chloride
Magnesium hypophosphite
Magnesium sulfate
Malachite green
Malic acid
Mangan sulfate
Marbofloxacin
Maropitant
Masitinib
Mavacoxib
Mebezonium iodide
Medetomidin
Medroxyprogesterone
Megestrol
Meloxicam
Menbuton
Menthol
Metamizol
Metergolin
Methimazol
Methionamin
Methopren
Methylene blue
Methylprednisolone
Methyl salicylate
Metronidazole
Miconazole
Milbemycin oxime
Miltefosin
Mometasone
Monensin
Monepantel
Moxidectin
Nafcillin
Nandrolon
Neomycin
Neostigmine
Netobimin
Nifurpirinol
Nitenpyram
Nitrofurazon
Nitroscanat
Nystatin

Oclacitinib
Omeprazole
Orbifloxacin
Osaterone
Oxalic acid
Oxantel
Oxfendazol
Oxytetracycline
Oxytocin
Paracetamol
Paraffin, liquid
Peforelin
Pegbovigrastim
Penethamate
Penicillin G-Procaine
Pentobarbital CD
Pentosanpolysulfate
Pergolide
Permethrin
Phenol
Phenoxyethanol
Phenylbutazone
Phenylpropanolamine
Phoxim
Phthalylsulfathiazol
Pimobendan
Pirlimycin
Polymyxin B
Polyvinylpyrrolidoniod
Posaconazole
Potassium chloride
Potassium iodide
Potassium permanganate
Potassium posphate
Pradofloxacin
Praziquantel
Prednisolone
Prifinium
Procaine
Progesteron
Proligeston
Propentofyllin
Propylenglycol
Prostaglandin E2
Prostaglandin F2α
Pyrantel
Pyriprole

Pyriproxifen
Ramipril
Resorcinol
Retinol
Robenacoxib
Romifidin
Ropinirole
S-Ketamine
Saccharose
Salicylic acid
Sarolaner
Selamectin
Selegilin
Sevoflurane
Sodium acetate
Sodium bicarbonate
Sodium chloride
Sodium lactate
Sodium lauryl sulfate
Sodium phosphate
Sodium proponate
Sodium selenite
Sorbitol
Spectinomycin
Spinosad
Spiramycin
Spironolactone
Sulfachlorpyridazin
Sulfaclozin
Sulfadiazin
Sulfadimidin
Sulfadoxin
Sulfaguanidin
Sulfamethoxazol
Sulfamethoxypyridazin
Sulfathiazol
Suxibuzon
Tannin
Telmisartan
Terbinafine
Tetracain
Tetracycline
Thiamin
Thiostrepton
Thymol
Tiamulin
Tildipirosin

Tiletamin
Tilmicosin
Toceranib
Tocopherol
Tolfenamic acid
Toltrazuril
Torasemide
Triamcinolone
Trichlormethiazide
Triclabendazole
Trilostan
Trimethoprim
Tulathromycin
Tylosine
Tylvalosin
Valnemulin
Vedaprofen
Vitamin B6
Whey proteins
Vaselinum album
Xylazin
Zinc sulphate
Zolazepam CD

Vaccines
Aujeszky's disease virus
Avian Encephalomyelitis virus
Avian Herpesvirus
Avian Influenza virus
Avian Infectious Anemia virus
Avian Infectious Bronchitis virus
Avian Infectious Bursitis virus
Avian Paramyxovirus
Avian Rhinotracheitis virus
Babesia canis canis
Bordetella bronchiseptica
Borrelia burgdorferi
Bovine Coronavirus
Bovine Herpesvirus
Bovine Orbivirus
Bovine Parainfluenza virus
Bovine Reovirus (Bluetongue virus)
Bovine respiratory syncytial virus
Bovine Rotavirus
Bovine viral diarrhoea vaccine
Canine Adenovirus
Canine Herpesvirus

Canine Parainfluenza virus
Canine Parvovirus
Canine distemper virus
Chlamydophila abortus
Chlamydophila felis
Chimaeric flavivirus
Clostridium botulinum
Clostridium chauvoei
Clostridium haemolyticum
Clostridium novyi
Clostridium perfringens
Clostridium septicum
Clostridium sordelli
Clostridium tetani
Coxiella burnetii
Dichelobacter nodosus
Dictyocaulus viviparus
Eimeria acervulina
Eimeria brunetti
Eimeria maxima
Eimeria mitis
Eimeria necatrix
Eimeria praecox
Eimeria tenella
Equine Herpes vaccine
Equine Influenza vaccine
Equine Tetanus toxoid
Erysipelothrix rhusiopathiae
Escherichia coli
Feline Calicivirus
Feline canarypox virus
Feline Coronavirus
Feline Herpesvirus
Feline Leukosevirus
Feline Parvovirus
Fimbrial adhesin
Foot-and-mouth disease vaccine
Haemoglobin glutamer (bovine)
Haemophilus parasuis
Lawsonia intracellularis
Leishmania infantum
Leptospira australis
Leptospira canicola
Leptospira grippotyphosa
Leptospira icterohaemorrhagiae
Leptospira interrogans
Leptospira kirschneri

Mannheimia haemolytica
Marine algae
Microsporum canis
Microsporum gypseum
Moraxella bovis
Muscovy duck parvovirus
Mycobacterium avium
Mycobacterium bovis
Mycoplasma synoviae
Myxoma-vectoredrabbit-haemorrhagic-disease virus
Ovines Parapox virus
Ornithobacterium rhinotracheale
Pasteurella multocida
Pasteurella trehalosi
Porcine Circovirus
Porcine Parvovirus
Porcine respiratory and reproductive syndrome virus
Rabbit haemorrhagic disease type 2 virus
Rabies virus
RecombinantShiga-toxin-2e antigen
Saccharomyces cerevisiae
Salmon pancreas disease vaccine
Schmallenberg virus
Staphylococcus aureus
Streptococcus equi
Streptococcus uberis vaccine
Swine Fever virus
Trichophyton equinum
Trichophyton mentagrophytes
Trichophyton sarkisovii
Trichophyton verrucosum
West-Nile-Virus

SCHEDULE 6

DIAGNOSTIC PRODUCTS AND AGENTS

1. Fluorescein (diagnostic eye strips)
2. Rapid Diagnostic Tests (RDTs)
3. Tuberculin (purified protein derivative)

Includes also all in-vitro diagnostics (IVDs) as listed in the published World Health Organisation (WHO) Model List of In Vitro Diagnostics or any other diagnostic product as approved by an internationally recognised Regulatory Authority.

SCHEDULE 7

COSMETICS

Includes all cosmetic products as defined in the Act and these Regulations.

SCHEDULE 8

HOMEOPATHIC MEDICINES

This Schedule includes all homeopathic medicines listed in a Pharmacopeia recognised by the Agency such as French Pharmacopoeia, German Homeopathic Pharmacopoeia, Homeopathic Pharmacopoeia of the United States, Homeopathic Pharmacopoeia of India, European Pharmacopoeia.

SCHEDULE 9

MEDICAL DEVICES

Includes all medical devices as classified by the World Health Organization and any other medical device recognised as such by the Agency.

SCHEDULE 10

HOUSEHOLD CHEMICAL SUBSTANCES

Includes all household chemical substances as defined in the Act and these Regulations.

SCHEDULE 11

LIST FOR PHARMACIES

Includes all medicines and related products listed in Schedules.

SCHEDULE 12

LIST FOR DRUGSTORES

a) Over The Counter (OTC) medicines excluding any parenteral preparation

1. Antipyretic, Analgesic
   Paracetamol (Acetaminophen)
2. Non-Steroidal Anti-inflammatory Drugs (NSAIDs)
   Ibuprofen (200mg, 400mg), Acetylsalicylic acid (Aspirin), Diclofenac (25mg) and topical preparations
3. Analgesic combination
   Paracetamol and Ibuprofen (200mg)
4. Antihistamines and Antiemetics
   Topical preparations
5. Antacids,
   Algicon and its analogues, Magnesium, Aluminium, Sodium, Calcium, Simethicone and Bismuth containing antacids, Milk of Magnesia
6. Antidiarrhoeals
   Oral Rehydration Salts (ORS), Loperamide, Kaolin and Pectin containing compounds
7. Antiseptics, disinfectants and cleansing agents for topical applications
   Cetrimide, Chlorhexidine, Glutaraldehyde, Magnesium sulphate powder, Phenol (Lysol)
8. Wound disinfectants for topical applications
   Gentian violet (Crystal violet) paint, Hydrogen peroxide, Povidone Iodine, Iodine, Mercurochrome
9. Antiscabies and Warts preparations
   Benzyl benzoate, Podophyllin, Silver nitrate
10. Antimalarials
    Artemether + Lumefantrine, Sulphadoxine + Pyrimethamine 500mg/25mg, Amodiaquine + Artesunate, Artesunate suppository, Artemether suppository, Dihydroartemisinin suppository, Dihydroartemisinin + Piperaquine tabs
11. Antihelminthics
    Albendazole, Mebendazole
12. Antihaemorrhoids
    Topical preparations
13. Cold preparations including nasal decongestants containing Ephedrine
14. Cough preparations except those containing Morphine and its analogues (e.g. Codeine)

15. Laxatives
    Liquid paraffin, Glycerin, Castor oil, Senna Tablets, Senna liquid
16. Contraceptive foaming tablets
17. Oral Contraceptives, low dose containing not more than 35 mcg Oestrogen or Progestrogen except for emergency
    Norgestrel + Ethinylestradiol, Levonorgestrol
    Levonorgestrol 150mcg + Ethinylestradiol 30mcg tabs
    Levonorgestrol 30mcg tabs
    Cyproterone acetate 2 mg + Ethinylestradiol 35mcg tablets
18. Glucose (Dextrose) powder
19. Emollients and protective
20. Aural preparations
    Olive oil
21. Topical counter irritants
    Crotamiton, Calamine lotion
22. Topical antifungals
    Nystatin preparations, Benzoic acid + Salicylic compound, Clotrimazole preparations, Miconazole, Ketoconazole shampoo
23. Topical acne & pimples preparations
    Benzoyl peroxide, Salicylic acid, Sulphur, Almond oil
24. Ophthalmic preparations
    Tetracycline, Chloramphenicol, Eye wash solutions
25. Topical antibiotics
    Tetracycline, Gentamycin, Neomycin & Bacitricin, Silver sulphadiazine
26. Oral Antibiotics
    Cotrimoxazole (Sulphamethozaxole + Trimethoprim) preparations only
27. Oral Vitamins and Minerals preparations
28. Oral Antianaemics
    Ferric and Ferrous salts and their combinations, Folic acid, Vitamin B12, Blood tonics
29. Antidotes
    Activated charcoal
30. Nutritional Supplements preparations
31. Water for injection

b) Prescription only Products to be given to patients if a prescription by an authorised prescriber is provided

Note: 'mcg' refers to microgramme (µg)

Acyclovir (5% cream)
Adrenaline (Epinephrine) 1mg/ml injection
Aminophylline 100mg tabs
Amitriptyline (25mg)

Amlodipine (5mg tabs)
Amoxycillin (125mg/5ml powder for syrup, 250mg/ 500mg capsules)
Ampicillin (oral)
Ampiclox (250mg/5ml syrup, 500mg capsules)
Atenolol (50mg tabs)
Beclomethasone 50mcg/dose inhaler
Bendrofluazide (2.5mg, 5mg tabs)
Betamethasone (0.1% ointment)
Bisacodyl (5mg tabs)
Bismuth subgallate 100mg + Zinc oxide 100mg + Lignocain 60mg suppositories
Calcium salts
Captopril 25mg tablets
Carbamazepine (200mg tabs)
Chlorpheniramine (4mg tabs)
Chlorpromazine (25mg, 100mg tabs)
Cimetidine (not more than 200mg)
Ciprofloxacin (250mg, 500mg tabs)
Cloxacillin (250mg tabs, capsules, 125mg/5ml powder for syrup)
Diclofenac (50mg, 100mg tabs)
Dihydralazine (25mg tabs)
Doxycycline (100mg tabs, capsules)
Enalapril (5mg tabs)
Ergometrine (0.5mg tabs)
Erythromycin (125mg/5ml (as ethyl succinate) syrup, 250mg (as stearate) tabs/capsules)
Flucloxacillin (250mg capsules)
Fluconazole (50mg capsules)
Furosemide (40mg tabs)
Glibenclamide (5mg tabs)
Glucose (Dextrose) (5% hypertonic injection, 50% Isotonic injection)
Griseofulvin (125mg, 500mg tabs)
Hydralazine (25mg tabs)
Hydrochlorothiazide (25mg, 50mg tabs)
Hydrocortisone (1% cream)
Hyoscine butylbromide (10mg tabs)
Ibuprofen (600mg tabs)
Ketoconazole (200mg tabs)
Lactulose (3.1/3.7g/ml)
Levamisole (40mg tabs)
Levonogestrel 750mcg (emergency contraceptive pill, may not require prescription)
Metformin (500mg tabs)
Methyldopa (250mg tabs)
Metoclopramide (10mg tabs)
Metronidazole (250mg, 500mg tabs, 500mg vaginal tabs)
Niclosamide (500mg tabs)

Nifedipine (10mg/20mg tabs, capsules)
Nitrofurantoin (100mg tabs)
Nystatin (100,000 iu oral suspension, 100,000 and 500,000 iu tabs)
Omeprazole (10mg tabs)
Phenytoin (100mg tabs)
Phenoxymethyl penicillin (Penicillin V) (250mg, 500mg tabs, 125mg/5ml suspension)
Prednisolone (0.5% eye drops, 5mg tabs)
Promethazine (25mg tabs, 5mg/5ml suspension)
Propranolol (40mg tabs)
Pyrimethamine (25mg tabs)
Quinine (300mg tabs)
Ranitidine (150mg tabs)
Retinol (Vitamin A) 200,000 IU/6mg capsules
Salbutamol (2mg, 4mg tabs, 2mg/5ml suspension, 100mcg/dose)
Sodium chloride (0.9% intravenous solution)
Sodium cromoglycate (2% eye drops)
Spironolactone (25mg tabs)
Timolol (0.25%, 0.5% eye drops)
Tropicamide (1% eye drops)
Zinc oxide (10% ointment)
Zinc sulphate (10mg tabs)

c) Diagnostic Agents

- Rapid Diagnostic Tests (RDTs)

d) Related Products

- Condoms (male and female)
- Gloves, masks, cotton wool,
- Syringes and needles
- Bandages & Plasters
- Household Insect sprays
- Lubricants, Olive oil, Almond oil
- Antiseptic body and face wash
- Hand sanitizers
- Emollients and Protective
- Dental Preparations, mouthwash, toothpaste, toothbrushes, dental floss, dental brushes, antiseptic mouth gels

Includes in addition, all Cosmetics addressed in Schedule 7.

SCHEDULE 13

LIST FOR SUPERMARKETS

1. Antipyretic analgesic
   Paracetamol
2. Non-Steroidal Anti-inflammatory Drugs (NSAIDs)
   Ibuprofen (200mg), Acetyl salicylic acid and topical preparations
3. Analgesic combination
   Paracetamol and Ibuprofen (200mg)
4. Antacids, Algicon and its analogues
   Magnesium, Aluminium, Sodium, Calcium, Simethicone and Bismuth containing antacids, Milk of Magnesia
5. Antidiarrhoeals
   Oral Rehydration Salts (ORS), Kaolin and Pectin containing compounds
6. Antiseptics, disinfectants and cleansing agents
   Cetrimide, Chlorhexidine, Gentian Violet paint, Hydrogen peroxide, Povidone Iodine, Mercurochrome
7. Cold & Cough preparations, excluding Ephedrine, Codeine, Morphine and their analogues
8. Cold preparations including inhalants, essential volatile oils, balms and rubs
9. Liniments, ointments, creams and rubs for pain relief excluding steroid-containing combinations
10. Laxatives
    Glycerin, Castor oil
11. Oral Glucose preparations
12. Topical Insect repellants
13. Topical counter irritants
    Calamine lotion
14. Nutritional Supplements preparations including oral Vitamins and Minerals preparations
15. Related Products
    - Condoms (male and female)
    - Bandages & Plasters
    - Household Insect sprays
    - Lubricants, Olive oil, Almond oil
    - Antiseptic body and face wash

- Hand sanitizers
- Emollients and Protective
- Dental Preparations, mouthwash, toothpaste, toothbrushes, dental floss, dental brushes, antiseptic mouth gels

Includes in addition, all Cosmetics addressed in Schedule 7.

DATED THIS ..... DAY OF..... 2020.

.....
HON. DR. AHMADOU SAMATEH
MINISTER OF HEALTH