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THE TANZANIA FOOD, DRUGS AND COSMETICS ACT
ARRANGEMENT OF REGULATIONS

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THE TANZANIA FOOD, DRUGS AND COSMETICS ACT
2003
(No. 1 OF 2003)

REGULATIONS

Made under Section 122(1) (p)

THE TANZANIA FOOD, DRUGS AND COSMETICS (CLINICAL TRIALS
CONTROL) REGULATIONS, 2011

PART I
PRELIMINARY PROVISIONS

Short title and
Commencement

1. These regulations may be cited as the Tanzania Food, Drugs and Cosmetics (Clinical Trials Control) Regulations, 2013.

Interpretation

2. In these regulations, unless the context otherwise requires-

Cap. 219

“Act” means the Tanzania Food, Drugs and Cosmetics Act;

“adverse drug reactions” means all noxious and unintended responses to an investigational medicinal product related to any dose or all unintended noxious responses to a registered medicinal product which occurs at doses normally used in humans for prophylaxis, diagnosis, or therapy of diseases or for modification of physiological function;

“adverse event” means any untoward medical occurrence in a patient or study participant administered a pharmaceutical product and which does not necessarily have a causal relationship with the treatment;

“applicant” means a person and including a Sponsor,

Contract Research Organization or in the case of investigator-initiated academic research studies, research institution or principal investigator, applying for permit to conduct a clinical trial;

“assembled” in relation to investigational medicinal product means and include-

(a) enclosing the product, with or without other medicinal products of the same description, in a container which is labelled before the product is used or supplied; or

(b) where the product, with or without other medicinal products of the same description, is already enclosed in the container in which it is to be used or supplied, and is labelled before the product is used or supplied;

“Authority” means the Tanzania Food and Drugs Authority or its acronym “TFDA” established under section 4 of the Act;

“blinding or masking” means a procedure in which one or more parties to a clinical trial are kept unaware of the treatment assignment;

“case report form” means a document that is used to record data on each study participant during the course of the trial, as defined by the protocol;

“clinical trial or study” means an investigation or series of investigations consisting of a particular description by, or under the direction of a medical practitioner, dentist or veterinary surgeon to the patient or animal where there is evidence that drugs, medical devices or herbal drugs of that description has effects which may be beneficial to and safe to the patient and animal in question and the administration of the drugs, medical devices or herbal drugs is for the purpose of ascertaining beneficial and harmful

- effects;
- “clinical trial or study report” means a written description of a clinical trial or study of any therapeutic or prophylactic agent conducted in human study participants in which the clinical and statistical description, presentations and analyses are fully integrated into a single report;
- “clinical trial site” means an investigator site, Sponsor’s office, contract research organization, data management centre or any other establishment involved in a clinical trial;
- “code” means identification code assigned by the investigator to each clinical trial study participant to protect the study participant's identity and used in lieu of the study participant's name when the investigator reports adverse events or other trial related data;
- “confidentiality” means maintenance of the privacy of trial participants including their personal identity and all personal medical information;
- “coordinating investigator” means an investigator assigned the responsibility for the coordination of investigators at different centres participating in a multi-centre trial;
- “contract research organization” means a person or an organization contracted by the Sponsor to perform one or more of a Sponsor trial-related duties and functions;
- “data and safety monitoring board” means an independent data monitoring committee that may be established by the Sponsor to assess at intervals the progress of a clinical trial, the safety data and the critical efficacy endpoints and to recommend to the Sponsor whether to continue, modify, or stop a trial;
- “direct access” means permission to examine, analyze, verify and reproduce any records and reports that are important to evaluation of a clinical trial;

- essential documentsö means documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced;
- ethical clearanceö means an authorization to conduct a clinical trial issued by an approved institute for medical research;
- good clinical practiceö means a standard for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials that provide assurance that the data and reported results are credible and accurate and that the rights, integrity, and confidentiality of study participants are protected;
- good manufacturing practiceö means that part of quality assurance which ensures that investigational medicinal products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization;
- herbal drug" means any labeled preparation in pharmaceutical dosage form that contains one or more substances of natural origin as active ingredients that are derived from plants;
- informed consentö means participant voluntary confirmation of willingness to participate in a particular trial, and the documentation thereof;
- inspectionö means the act of conducting an official review of documents, facilities, records, and any other resources that are deemed by the Authority to be related to the clinical trial and that may be located at the clinical trial site;
- investigational medicinal productö in relation to a drug, medical device and herbal drug means a pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a

- marketing authorization when used or assembled in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use;
- “investigator” means a physician, dentist or other qualified person who conducts a clinical trial at a trial site;
- “investigator brochure” means a compilation of the clinical and non-clinical data on the investigational product which is relevant to the study of the investigational product in human study participants;
- “monitor” means a person appointed by, and responsible to, the Sponsor or Contract Research Organization for the monitoring and reporting of progress of the trial and for verification of data;
- “multi-centre clinical trial” means a clinical trial conducted according to a single protocol but at more than one site, and therefore, carried out by more than one investigator;
- “National Ethics Committee” means an independent body in Tanzania constituted of medical professionals and non-medical members, whose responsibility is to verify that the safety, integrity and human rights of participants in a particular trial are protected and to consider the general ethics of the trial, thereby providing public reassurance. National Ethics Committee shall be constituted and operated so that its tasks can be executed free from bias and from any influence of those who are conducting the trial;
- “national registry” means a database created by the Authority that houses and manages information about a clinical trial submitted by an applicant;
- “pharmacovigilance” means the science and activities

- relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem;
- “pre-clinical studies” means biomedical studies not performed on human study participants;
- “principal investigator” means a pharmacist, physician, dentist, veterinarian or other qualified person, resident in Tanzania Mainland and member of good standing of a professional body, responsible for the conduct of clinical trial at a clinical trial site;
- “product” means investigational medicinal product;
- “protocol” means a document which states the background, rationale and objectives of a clinical trial and describes its design, methodology and organization, including statistical considerations, and the conditions under which it is to be performed and managed;
- “protocol amendment” means a written description of changes to or formal clarification of a protocol;
- “quality assurance” means all those planned and systematic actions that are established to ensure that a trial is performed and data are generated, documented, recorded, and reported in compliance with good clinical practice;
- “quality control” means the operational techniques and activities undertaken within a quality assurance system to verify that the requirements for quality of the clinical trial-related activities have been fulfilled;
- “randomization” means the process of assigning study participants to treatment or control groups using an element of chance to determine the assignments in order to reduce bias;
- “serious adverse event or serious adverse drug reactions” means any untoward medical occurrence that at any dose may cause any of the following:
- (a) death;

- (b) life threatening;
 - (c) hospitalization or prolongation of existing hospitalization;
 - (d) persistent or significant disability or incapacity; or
 - (e) congenital anomaly or birth defect;
- ōsponsorö means an individual, company, institution or organization who takes responsibility for the initiation, management and, or financing of a clinical trial;
- ōtrial or study participantö means an individual who participates in a clinical trial either as a recipient of the investigational medicinal product or as a control;
- ōtrial or study siteö means the location(s) where clinical trial-related activities are conducted;
- ōunexpected adverse drug reactionö means an adverse reaction, the nature or severity of which is not consistent with the applicable product information; and
- ōveterinarianö means any person who has been awarded a degree in veterinary medicine or its equivalent from a veterinary institution recognized by the Veterinary Council.

PART II

APPLICATION FOR AUTHORIZATION TO CONDUCT CLINICAL TRIALS

Conduct of clinical trials

3. No person shall conduct a clinical trial of any drug, medical device or herbal drug without the written authorization issued by the Authority.

Application to conduct clinical trials

4.-(1) An application to conduct a clinical trial of an investigational medicinal product shall be submitted to the Authority and accompanied by the following-

- (a) covering letter to the Authority;

- (b) duly filled in, signed and stamped application in the form provided in the First Schedule to these Regulations;
- (c) general investigational plan;
- (d) capacity building plans including training and updating of staff involved in the trial;
- (e) current version of the study protocol signed and dated by sponsor and investigator;
- (f) investigator's brochure or prescribing information data sheet as provided in the guidelines for application to conduct clinical trials;
- (g) informed consent information or forms as provided in the guidelines for application to conduct clinical trials;
- (h) declaration by principal investigator as provided in the Second Schedule to these Regulations;
- (i) declaration by monitor as provided in the Third Schedule to these Regulations;
- (j) financial declaration by sponsor and Principal investigator as provided in the Fourth Schedule to these Regulations;
- (k) certified copy of insurance of study participants;
- (l) ethical clearance certificate, or a copy of acknowledgement of submission of study protocol, from any approved institute for medical research;
- (m) investigational medicinal product dossier as provided in the guidelines for application to conduct clinical trials;
- (n) application fees as prescribed in the Fees and Charges Regulations in force at the time of application; and
- (o) any other requirement as may be

determined by the Authority.

(2) An application to conduct a clinical trial may be made by a sponsor or the sponsor's agent who shall submit a power of attorney attesting that he is a duly appointed agent.

Conditions for authorization of clinical trials

5.-(1) Authorization for a clinical trial shall be granted to the following categories of medicines-

- (a) unregistered medicines; or
- (b) registered medicines where the proposed clinical trials are outside the conditions of approval and may include changes to-
 - (i) indications and clinical use;
 - (ii) target patient population(s);
 - (iii) routes of administration ; and
 - (iv) dosage.

(2) Subject to Regulation 5 and sub-regulation (1) to this regulation, the Authority shall not authorize a clinical trial where it is satisfied that-

- (a) the information and documents as set out in these Regulations have not been provided;
- (b) the application contains false or misleading information;
- (c) the information provided is insufficient to enable the Authority assess the safety and risks of the investigational medicinal product or clinical trial;
- (d) queries raised by the Authority in relation to the application made to it were not adequately responded to;
- (e) the applicant has not submitted an ethical clearance from any approved institute for medical research;
- (f) the use of the drug, medical device or herbal drug for the purposes of the clinical trial endangers the health of a

clinical trial participant or any other person;

- (g) the objectives of the clinical trial will not be achieved;
- (h) it is not in the public interest to authorize the clinical trial; and
- (i) any other reasonable grounds as may be determined by the Authority.

Amendment to
clinical trials

6.-(1) Any amendment to an approved clinical trial application shall be notified to the Authority.

(2) The amendment referred to in sub-regulation (1) shall not be implemented without a written authorization from the Authority if they have the following-

- (a) affect patient selection and monitoring;
- (b) affect clinical efficacy and safety requirements;
- (c) affect patient discontinuation;
- (d) include addition or closure of an investigational site;
- (e) lead to change of principal investigator;
- (f) result in the extension of duration of a clinical trial; or
- (g) relate to the chemistry and manufacturing information that may affect drug safety and quality.

(3) An application for amendment to an approved clinical trial shall be made in the form provided in the Fifth and Sixth Schedules to these Regulations and accompanied by amendment fees as prescribed in the Fees and Charges Regulations in force at the time of application.

(4) An application for amendment to an approved clinical trial shall be accompanied by Ethical Clearance certificate from the National Ethics Committee.

(5) Any person who contravenes any provision to this regulation shall be guilty of an

offence under the Act.

PART III
NATIONAL REGISTRY FOR CLINICAL TRIAL INFORMATION

- National registry
- 7.-(1) Applicants for conduct of clinical trials shall be required to register a clinical trial in the National Registry established by the Authority.
- (2) The clinical trial information required to be provided in the National Registry under this regulation shall include-
- (a) descriptive information including-
 - (i) a brief title, intended for the lay public;
 - (ii) a scientific title as it appears in the protocol including trial acronym, if available;
 - (iii) a brief summary, intended for the lay public;
 - (iv) the primary purpose;
 - (v) the study design;
 - (vi) for an applicable drug clinical trial, the study phase;
 - (vii) study type;
 - (viii) the primary disease or condition being studied, or the focus of the study;
 - (ix) the intervention name and intervention type;
 - (x) the study start date;
 - (xi) the expected completion date;
 - (xii) the target number of participants; and
 - (xiii) outcomes, including primary and secondary outcome measures;
 - (b) recruitment information, including-

- (i) eligibility criteria;
 - (ii) gender;
 - (iii) age limits;
 - (iv) whether the trial accepts healthy volunteers;
 - (v) overall recruitment status; and
 - (vi) individual site status.
- (c) location and contact information, including;
- (i) name of the sponsor;
 - (ii) name of the applicant; and
 - (iii) facility name and facility contact information such as the city, phone number, fax number and email address through which such location information may be accessed.
- (d) administrative data including-
- (i) unique protocol identification number;
 - (ii) other protocol identification numbers, if any;
 - (iii) the application number assigned by the Authority; and
 - (iv) the date of registration of the clinical trial in the National Registry.

(3) The Authority may modify the requirements for clinical trial information under sub-regulation (2), if a *rationale* is provided as to why such a modification shall not be imposed and that such modification does not reduce such clinical trial information.

(4) The National Registry shall ensure that the public may, in addition to keyword searching, search the entries in the National Registry by one or more of the following criteria-

- (a) the disease or condition being studied in

the clinical trial;

- (b) the name of the intervention, including any drug or device being studied in the clinical trial;
- (c) the location of the clinical trial;
- (d) the age group studied in the clinical trial, including pediatric subpopulations;
- (e) the study phase of the clinical trial;
- (f) the Sponsor of the clinical trial;
- (g) the recruitment status of the clinical trial; and
- (h) the National Clinical Trial number or other study identification for the clinical trial.

(5) The National Registry shall ensure that the public may search the entries of the registry by such other elements as the Authority deems necessary on an ongoing basis.

(6) An applicant shall submit to the custodian of the National Registry for inclusion in the National Registry, the clinical trial information described in sub-regulation (2) not later than twenty one days after the first patient is enrolled in such a clinical trial.

(7) The National Registry shall ensure that clinical trial information submitted in accordance with sub-regulation (6) is posted in the National Registry not later than thirty days after such a submission.

(8) The Director General in consultation with the custodian of the National Registry shall-

- (a) expand the National Registry to include the status and results of clinical trials;
- (b) ensure that such results are made publicly available;
- (c) post publicly a glossary for the lay public explaining technical terms related to the results of clinical trials; and in consultation with experts on risk communication, provide information

with the information included under sub-regulation (2) in the National Registry to help ensure that such information does not mislead the patients or the public.

PART IV
GOOD CLINICAL PRACTICE AND THE CONDUCT OF CLINICAL TRIALS

Good Clinical Practices

8.-(1) An investigator or sponsor shall ensure that a clinical trial is conducted in accordance with but not limited to the following Good Clinical Practice requirements-

- (a) a trial shall be initiated and continued only if the anticipated benefits justify the risks;
- (b) the rights, safety, and well being of the trial study participants shall prevail over the interests of science and society;
- (c) the available pre-clinical and clinical information on an investigational medicinal product shall be adequate to support the proposed clinical trial;
- (d) clinical trials shall be scientifically sound, and described in a clear and detailed protocol;
- (e) a clinical trial shall be conducted in compliance only with a protocol that has received authorization from the Authority;
- (f) the medical care given to, and medical decisions made on behalf of study participants shall be the responsibility of a qualified physician or, when appropriate, of a qualified dentist;
- (g) each individual involved in conducting a trial shall be qualified by education,

- training and experience to perform his respective duties;
- (h) freely given informed consent shall be obtained from every study participant prior to clinical trial participation;
 - (i) clinical trial information shall be recorded, handled, and stored in a way that enables its accurate reporting, interpretation and verification;
 - (j) the confidentiality of records that could identify study participants shall be protected;
 - (k) investigational medicinal product shall be manufactured, handled, and stored as provided in the guidelines for good manufacturing practices and shall be used in accordance with the approved protocol; and
 - (l) systems with procedures that assure the quality of every aspect of the trial shall be implemented.

Qualifications of
investigators and
monitors

9.-(1) In any clinical trial, the Authority may approve the principal investigator who is declared in the study protocol upon satisfaction that, he has the following minimum qualifications and experience-

- (a) a university degree in medicine or pharmacy or pharmacology or toxicology or biochemistry or veterinary or dentist and related fields;
- (b) practical experience within the relevant professional area;
- (c) resident in Tanzania;
- (d) previous experience as a co-investigator in at least two trials in the relevant professional area; and
- (e) evidence of a good standing professional conduct.

(2) Monitors shall be appointed by the sponsor and shall be appropriately trained, and have the scientific and, or clinical knowledge needed to monitor the trial adequately.

Responsibilities of
Principal Investigator

10.-(1) The principal investigator shall be responsible for the conduct of the clinical trial at the investigator site.

(2) In case of multi-centre studies where the principal investigator is not a resident of Tanzania, the principal investigator shall be a resident in Tanzania and shall assume full responsibilities for all local investigator sites.

(3) The principal investigator shall maintain a list of appropriately qualified persons to whom he has delegated significant trial-related duties.

(4) The principal investigator shall ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational medicinal product, and their trial-related duties and functions.

(5) The principal investigator shall ensure that adequate medical care is provided to a study participant for any adverse events, including clinically significant laboratory values, related to the trial.

(6) The principal investigator shall comply with the protocol approved by the Authority.

(7) The principal investigator shall be responsible and accountable for the investigational medicinal product at the trial site.

(8) The principal investigator may assign all duties for investigational medicinal product accountability at the trial site to an appropriate pharmacist or another appropriate individual who shall be under the supervision of the investigator.

(9) The principal investigator shall follow the randomization procedures, if any, and shall ensure that the code is broken only in accordance with the

protocol.

Responsibilities of
sponsor

11.-(1) The sponsor shall implement and maintain quality assurance and quality control systems to ensure that trials are conducted and data are generated, documented, recorded and reported in compliance with the protocol, good clinical practice and these Regulations.

(2) The sponsor shall ensure that agreements are made between parties involved and the Authority have direct access to all trial related sites, source data and documents and reports for the purpose of inspection.

(3) The sponsor shall ensure that all agreements made with the Principal Investigator and any other parties involved in a clinical trial are in writing, as part of the protocol or in a separate agreement.

(4) Transfer of any or all of the sponsor's trial-related duties and functions to a third party shall not exonerate from liability to the sponsor.

(5) The sponsor shall provide insurance for trial participants or indemnify the investigator against claims arising from the trial, except for claims that arise from malpractice or negligence.

(6) The sponsor shall ensure that sufficient safety and efficacy data from pre-clinical studies and, or clinical trials are available to support human exposure by the route, at the dosages, for the duration, and in the trial population to be studied.

(7) The sponsor shall update the investigator brochure at any time when new significant information becomes available.

Insurance of trial
participants

12. The Authority shall satisfy itself that all subjects of the trial are satisfactorily insured against possible injuries that might arise during the conduct of a clinical trial in accordance with the laws of Tanzania.

(2) For all sponsor-initiated trials, a valid insurance certificate from a recognized insurer for the duration of the study shall be provided prior to study initiation.

(3) For investigator-initiated research trials, proof of current malpractice insurance that covers clinical trials shall be provided to the Authority.

Progress reports

13.-(1) The principal investigator or sponsor shall submit written clinical trial progress reports annually, or more frequently, as may be required by the Authority.

(2) After the completion of the clinical trial, the principal investigator or sponsor shall submit a final study report to the Authority in accordance with the format provided by the Authority.

Good Clinical Practice training

14. Prior to commencement of a clinical trial, a proof of training in good clinical and laboratory practices conducted within the last three years shall be submitted by the applicant to the Authority.

Records and record keeping

15.-(1) Without prejudice to any regulation, the investigator and sponsor shall keep in safe custody all records, documents and information related to a clinical trial at the clinical trial site for a period of not less than twenty years after completion of a trial.

(2) Unless there are pending or contemplated marketing applications, essential documents used in clinical trials shall be retained for at least two years after the last approval of a marketing application.

(3) The Authority may require the principal investigator or sponsor to submit to it records, documents and information stored under sub-regulation (1) when it may deem fit and just.

(4) The principal investigator and sponsor shall maintain complete and accurate records to establish that the clinical trial is conducted in

accordance with good clinical practice and these Regulations.

(5) Without prejudice to any other requirement, the sponsor shall, in respect of the use of an investigational medicinal product in a clinical trial, maintain the following records-

- (a) a copy of all versions of the investigator brochure for the investigational medicinal product;
- (b) records respecting each change made to the investigator brochure, including the rationale for each change and documentation that supports each change;
- (c) records in respect of all adverse events of the investigational medicinal product that have occurred inside or outside Tanzania mainland, including information that specifies the indication for use and the dosage form of the investigational medicinal product at the time of the adverse event;
- (d) records in respect of the enrolment of clinical trial participants, including information sufficient to enable all clinical trial participants to be identified and contacted in the event that the sale of the investigational medicinal product may endanger the health of the clinical trial participants or other persons;
- (e) records in respect of the shipment, receipt, disposition, return and destruction of the investigational medicinal product; and
- (f) for each clinical trial site, a copy of the protocol, informed consent form and any amendment to the protocol or informed consent form that have been approved by the Authority for that clinical trial site.

(6) The principal investigator and, or pharmacist or other appropriate individual, who is

designated by the principal investigator, shall maintain records of the investigational medicinal product's delivery to the trial site, the inventory at the site, the use by each study participant, and the return to the sponsor or alternative disposition of unused product.

Discontinuation of a clinical trial by a Sponsor

16. Where a clinical trial is discontinued by a sponsor in its entirety or at a clinical trial site, the sponsor shall-

- (a) cause the information to reach the Authority not later than fifteen days after the date of the discontinuation;
- (b) provide the Authority with the reason for the discontinuation and its impact on the proposed or ongoing clinical trials in respect of the investigational medicinal product including issues related to accountability and disposal of investigational medicinal product;
- (c) as soon as possible, inform all investigators of the discontinuation and of the reasons for the discontinuation, and advise them in writing of any potential risks to the health of clinical trial participants or other persons; and
- (d) in respect of each discontinued clinical trial site, stop the use or importation of the investigational medicinal product as from the date of the discontinuation and take all reasonable measures to ensure the recovery of all unused quantities of the investigational medicinal product.

Suspension or termination of a clinical trial by the Authority

17.-(1) The Authority may, in relation to a clinical trial, by a notice served in accordance with sub-regulation (2), require that the clinical trial, or the conduct of the clinical trial at a particular clinical trial site, be suspended or terminated if satisfied that-

- (a) a condition, restriction or limitation

- which applies to the conduct of the trial and set out in the application for authorization or the particulars or documents accompanying that request;
- (b) a condition imposed by the Authority under any other regulation is no longer valid either generally or at a particular trial site; or
 - (c) there is information raising doubts about the safety or scientific validity of the trial, or the conduct of the trial at a particular trial site.
- (2) A notice in accordance with sub-regulation (1) shall be served-
- (a) in case where the suspension or termination applies to the clinical trial generally, on \acute{o}
 - (i) the sponsor; or
 - (ii) the investigator at each clinical trial site;
 - (b) in a case where the suspension or termination applies to the conduct of a clinical trial at a particular clinical trial site, on-
 - (i) the sponsor; or
 - (ii) the investigator at that clinical trial site.
- (3) The notice shall specify -
- (a) whether it applies to the clinical trial generally or to one or more of the clinical trial sites;
 - (b) whether it requires suspension or termination of the clinical trial;
- (4) Subject to sub-regulation (3), if such notice requires suspension of the clinical trial, it shall specify-
- (a) whether the suspension applies until further notice from the Authority or for such period as may be specified in the

notice;

- (b) any conditions which are to be satisfied before the trial or, as the case may be, the conduct of the trial at a particular site, may be recommended; and
- (c) whether suspension or termination is to take effect immediately on receipt of the notice or on such date as may be specified in the notice.

(5) If the Authority issues a notice under sub-regulation (1), it shall forthwith inform the sponsor and the principal investigator.

(6) Subject to sub-regulation (5), at least seven days before issuing a notice under sub-regulation (1), the Authority shall, by a notice in writing to the sponsor or the principal investigator-

- (a) inform sponsor or the principal investigator that the Authority is intending to issue a notice suspending or terminating the trial, or the conduct of a trial at a particular site, and of the reasons thereof; and
- (b) order the sponsor or the principal investigator that, within 7 days of the date of the notice, furnish the Authority with written representations as to whether the trial, or the conduct of the trial at a particular site, shall be so suspended or terminated.

(7) Sub-regulation (6) shall not apply where it appears to the Authority that there is an imminent risk to the health or safety of any of the participants of the clinical trial.

(8) A person on whom a notice has been served in accordance with sub-regulation (1) and (2) may, within twenty eight days, or such extended period as the Authority may in any particular case allow, of the notice being given, give notice of his wish to make written or oral representations to the

Authority.

(9) Where the notice of suspension or termination is referred to the Authority it shall remain in force unless revoked.

PART V
PHARMACOVIGILANCE

Notification of adverse events

18.-(1) The Principal Investigator shall immediately report to the Authority any serious adverse event which occurs in a study participant at a clinical trial site at which he is responsible for the conduct of a clinical trial.

(2) An immediate report under sub-regulation (1) may be made orally or in writing.

(3) Subject to sub-regulation (1), the investigator shall make a detailed written report on the event within fourteen days.

(4) Sub-regulation (1) to (3) does not apply to serious adverse events specified in the protocol or the investigator brochure.

(5) Adverse events, other than those to which sub-regulations (1) to (3) apply, that are identified in the protocol as critical to evaluations of the safety of the clinical trial shall be reported to the Authority.

(6) The reports made under sub-regulations (1), (3) and (5) shall identify each participant referred to in the report by a number assigned to that participant in accordance with the protocol for the clinical trial.

(7) The number assigned to a participant in accordance with the protocol shall be different from the number of any other participant in that clinical trial, including participant at any other trial site.

(8) The Authority may require additional information where the event reported under sub-regulation (1) or (5) consists of, or results in, the death of a participant.

Notification of suspected unexpected serious adverse reactions

19.-(1) The principal investigator or sponsor shall record and report to the Authority any suspected unexpected serious adverse reaction that is fatal or life-threatening which occurs during the course of a clinical trial, within seven days.

(2) The principal investigator or sponsor shall record and report to the Authority any suspected unexpected serious adverse reaction which occurs during the course of a clinical trial other than those referred to in sub-regulation (1), within fifteen days.

PART VI
MANUFACTURE AND IMPORTATION OF INVESTIGATIONAL
MEDICINAL PRODUCTS

Requirements for authorization to manufacture or import investigational medicinal products

20.-(1) No person, other than a person issued with a license or permit under the provisions of the Act, shall manufacture, assemble, import or export any investigational medicinal product.

(2) Notwithstanding the provision of sub-regulation (1), investigational medicinal products shall be manufactured in accordance with Good Manufacturing Practices.

(3) The provisions under sub-regulation (1) shall not apply to the assembly of an investigational medicinal product where such assembly is carried out in a hospital or health centre which is a clinical trial site for the clinical trial in which the product is to be used.

Application for manufacturing authorization, importation and exportation

21. Any application for the grant of a manufacturing, importation or exportation license or permit for an investigational medicinal product shall be made in accordance with the provisions of the Act.

Suspension or revocation of import permit or manufacturing authorization

22.-(1) The Authority may by a notice in writing to the holder of a license or permit, forthwith or from a date specified in the notice, suspend or

revoke the license or permit for such period as may determine, on one or more of the following grounds-

- (a) the holder is not carrying out, or has indicated by a notice in writing that he is no longer willing to carry out, the manufacturing, assembly or importation operations to which the license or permit relates;
- (b) the particulars accompanying the application in accordance with this regulation, were false or incomplete in a material particular;
- (c) a material change of circumstances has occurred in relation to any of those matters or particulars;
- (d) the holder of the license or permit has failed to any material extent to comply with any provision of these Regulations;
- (e) the holder of the license or permit has manufactured, assembled or, as the case may be, imported investigational medicinal products other than in accordance with the terms of the license or permit;
- (f) the holder of the license or permit has manufactured or assembled investigational medicinal products other than in accordance with \acute{o}
 - (i) in the case of products manufactured for the purpose of export, the specification for the product provided by the person to whom the order of the products are manufactured, or
 - (ii) in any other case, the specification for the product contained in the investigational medicinal product dossier;
- (g) the investigational medicinal product has

not been manufactured in accordance with Good Manufacturing Practices.

(2) The suspension or revocation of a license or permit under this regulation may be -

- (a) total;
- (b) limited to investigational medicinal products-
 - (i) of one or more descriptions, or
 - (ii) manufactured, assembled or stored in any particular premises or in a particular part of any premises.

(3) Any notification given under sub-regulation (1) shall include a statement of the intention of the Authority and the reasons thereof.

(4) A person to whom notification has been given under sub-regulation (3) may, within the time shown in the notice, show cause to the Authority as to why revocation or suspension of the license or permit may not be effected.

(5) The provisions of sub-regulation (1) shall have effect after the Authority has not been satisfied by the representation made to show cause as to why suspension or revocation cannot be issued.

PART VII LABELLING OF INVESTIGATIONAL MEDICINAL PRODUCTS

Labelling requirements

23.-(1) An investigational medicinal product shall be labeled in Kiswahili or English and shall contain the following minimum information-

- (a) statement indicating that the product is for ðclinical trial purpose onlyö;
- (b) name, number or identifying mark;
- (c) recommended storage conditions;
- (d) name and address of the Sponsor;
- (e) protocol code or identification.

(2) Where applicable, investigational medicinal products shall be labeled in the manner that protects the blinding.

(3) Re-labelling of any remaining investigational medicinal product from previously manufactured batches shall be performed in accordance with established written procedures and Good Manufacturing Practice principles.

**PART VIII
DATA AND SAFETY MONITORING COMMITTEES**

Requirements related to data and safety monitoring committees

24.-(1) The Authority reserves discretion to impose a condition for establishment of a Data and Safety Monitoring Board or Data Monitoring Committee.

(2) The establishment of a Data and Safety Monitoring Board or Data Monitoring Committee under sub-regulation (1) may depend upon the following-

- (a) the design and scientific background of the clinical trial;
- (b) the risk and benefit assessment of the clinical trial; and
- (c) any other reasons as may be determined by the Authority or Sponsor.

(3) In any case, where clinical trials involves Data and Safety Monitoring Board or Data Monitoring Committee to monitor clinical trials, the Authority may require the following information-

- (a) a broad statement of the aims and objectives;
- (b) terms of reference;
- (c) composition of members;
- (d) qualifications of members;
- (e) specific roles including responsibilities of statisticians;
- (f) the role of statistical stopping rules;
- (g) relationship with the principal investigators and trial; management team
- (h) clarification on the decision-making powers;
- (i) how meetings will be organized;

- (j) whether the members will be blinded to treatment
- (k) what options can be recommended;
- (l) in what form and to whom decisions will be conveyed;
- (m) a person to whom the committee will report to the role of the committee in the publication of results; and
- (n) disclosure of competing interests of the committee members.

**PART IX
INSURANCE AND INDEMNITY**

Insurance and
indemnity cover

25.-(1) Without prejudice to the contents of regulation 13, no clinical trial shall be conducted unless the sponsor provides insurance cover from an insurance company registered in Tanzania Mainland to any study participants against any clinical trial-related injuries or harms that may arise over the course of a clinical trial.

(2) Subject to sub-regulation (1), the sponsor shall indemnify the investigator against claims arising from the trial, except for claims that arise from malpractice and, or negligence.

(3) The insurance cover for study participants and investigators referred in sub-regulation (1) shall be in accordance with the applicable law in Tanzania Mainland.

**PART X
INSPECTION OF CLINICAL TRIALS**

Requirements for
inspection of clinical
trials

26.-(1) For the purposes of ensuring compliance with the protocol, Good Clinical Practice and these Regulations, the Authority may at all reasonable time inspect any clinical trial authorized to be conducted in Tanzania Mainland.

(2) Clinical trial inspection shall, among other things, ensure that participants are not subjected to

undue risks, to validate the quality of data generated and, or to investigate complaints.

(3) The Authority may take any legal action for any non compliance in accordance with the Act.

PART XI

OFFENCES AND PENALTIES

Offences and penalties

27. Any person, who contravenes any provision of these Regulations, shall be guilty of an offence under the Act.

Compounding of Offences

28.-(1) The Authority may, subject to and in accordance with the provisions of the Act, if circumstances show that a person, corporate or unincorporated body has committed any offence against these Regulations in respect to which he has showed willingness to pay a fine, compound such offence by accepting the fine or any other thing in respect of which the offence has been committed.

(2) Subject to the provisions of these Regulations authorizing any measures that may be taken pursuant to an order of the court, no further criminal or as the case may be, civil proceedings shall be taken by the Authority against a person in respect of whom a power to compound offence has been exercised.

(3) The Authority, may before accepting any fine prescribed under the Act shall require such a person to fill in a Compounding of Offence Form as provided in the Seventh Schedule to these Regulations.

FIRST SCHEDULE

Made under regulation 4(1)(b)

Clinical Trial Application Form

To be completed by Applicants for all Clinical Trials (in triplicate)

SECTION 1: GENERAL INFORMATION

| | |
|--|-------------|
| Study Title: | |
| Protocol No: | |
| Version No: | Date of |
| protocol: | |
| Investigational medicinal product's name, number or identifying mark | |
| Comparator product (if applicable): | |
| Concomitant medications (if applicable): | |
| Sponsor: | |
| Applicant: | |
| Contact Person: | |
| Address: | |
| Telephone Number: | Fax Number: |
| Cell phone Number: | |
| E-mail address: | |

| | |
|--|-------|
| FOR OFFICIAL USE ONLY | |
| Date original application received: | |
| Application/Reference No.: | |
| Application Fee paid: | |
| Signature: | Date: |
| <i>(All future communications to TFDA regarding the application should quote the above application/reference number)</i> | |

| | |
|--|--------|
| Acknowledgement of Receipt of Application (To be completed by TFDA receiving officer). Cover sheet to be sent to the applicant once details above are completed. | |
| Receipt of the application is hereby acknowledged. | |
| Name:í í í í í í í í í í í í í .. | |
| Signature:í í í í í í í í í í í í .. | |
| Date:í í í í í í í í í í í í í . | Stamp: |

SECTION 2: CHECKLIST AND TABLE OF CONTENTS (indicate pages)

- Cover sheet
- Covering letter
- Completed application form
- General investigational plan
- Capacity building plans including training and updating of staff involved in the trial
- Investigator's Brochure or prescribing information data sheet
- Protocols (study protocol and investigators, facilities and IEC data, informed consent forms and information given to participants)
- Declarations by Sponsor, monitors and investigators in prescribed format
- Financial joint declaration by Sponsor and Principal investigator
- Certified copy of insurance of study participants
- Ethical Clearance from the National Ethics Committee or copy of acknowledgement of submission of study protocol
- Investigational medicinal product dossier:
 - Chemistry, manufacturing and quality control data of active ingredient and finished product/dosage form
 - Pharmacology and toxicology data
 - Previous human experience data
 - Prototype product label

NB: incomplete applications will not be processed

SECTION 3: ADMINISTRATIVE AND SUPPLEMENTARY DETAILS

Title of the Study:

Protocol Number/Identification:

Version number

Date of final protocol:

Part 1: CONTACT DETAILS (including physical address)

- 1.1 Applicant:
- 1.2 Sponsor:
- 1.3 Local contact person:

- 1.4 Principal investigator:
- 1.5 International principal investigator: (if applicable)
- 1.6 Monitor:
- 1.7 Study coordinator:

Part 2: DETAILS OF INVESTIGATIONAL MEDICINAL PRODUCT(S)

- 2.1 Name(s) and details of IMP to be used in trial:
[A summary of the chemistry and manufacturing data, formulation, composition, excipients and strength should be provided. Complete chemistry and manufacturing data should be included in the investigator's brochure. Product(s) registration number(s) and date(s) of registration, if applicable, should be included]
- 2.2 Name(s) and details (as above) of comparator product(s) and product registration number(s) and date(s) of registration if applicable: [As in 2.1, where applicable. Prescribing information sheet for registered comparator products should be included]
- 2.3 Name(s) and details (as above) of concomitant medication(s) including rescue medications which are required in the protocol, and product registration number(s) if applicable [As in 2.1, where applicable. Prescribing information sheet for registered products should be included]
- 2.4 If any of the above IMPs are marketed locally, explain whether locally-sourced products will be used in the trial:
- 2.5 Details of packaging, storage conditions and shelf-life of IMP:
- 2.6 Registration status of IMP, for the indication to be tested in this trial, in other countries [i.e. Country: date registered / date applied for / date registration refused / date registration withdrawn by applicant / date registration cancelled by regulatory authority] [Attach as an appendix if necessary]

Part 3: DETAILS OF INVESTIGATORS AND TRIAL SITE(S)

Details of investigator(s):

[Designation and title of principal investigators/investigators) Include Name/Address/Tel/Mobile/Fax/E-Mail]

Current work-load of investigator(s):

[Number of studies currently undertaken by investigators as principal and/or co- or sub-investigator, and the total number of patients represented by these studies. Time-commitments of researcher(s) in relation to clinical trial work and non-trial work]

Details of Trial Site(s):

[Name of site, physical address, contact details, contact person, etc]

Capacity of Trial Site(s):

[Number of staff, names, qualifications, experience -- including study coordinators, site facilities, emergency facilities, other relevant infrastructure]

Part 4: TRIAL STUDY PARTICIPANTS

Number of local participants:

Total number of participants worldwide (where applicable):

Total enrolment in each local site/centre: [If competitive enrolment, state minimum and maximum number per site.]

Volunteer base from which local participants will be drawn

Retrospective data indicating potential of each site to recruit required number of participants within envisaged duration of trial: [Attach as an appendix if necessary]

Part 5: OTHER DETAILS

Provide an explanation if the trial is to be conducted locally only and not in the host country of the applicant / Sponsor:

Estimated duration of trial:

Details of other Regulatory Authorities to which applications to conduct this trial have been submitted, but approval has not yet been granted. Include date(s) of application:

Details of other Regulatory Authorities which have approved this trial. Include date(s) of approval and number of sites per country:

Details of other Regulatory Authorities or Research Ethics Committees which have rejected this trial, if applicable, and provide reasons for the rejection:

Details of and reasons for this trial having been suspended at any stage by other Regulatory Authorities, if applicable:

Previous studies using this agent which have been approved by the Authority:

Approval number:

Title of the study:

Protocol number:

Date of approval:

Principal Investigator:

Date(s) of progress report(s):

Date of final report:

If any sub-studies are proposed as part of this protocol, indicate whether these will also be conducted locally. If not, please explain:

Part 6: ETHICS

6.1 Research Ethics Committee responsible for each site, date of approval or date of application: [Attach copy of response(s) made by, and/or conditions required by Research Ethics Committee(s) if available]

6.2 Details of capacity building component of the trial, if any:

6.3 Details of International Conference on Harmonization-Good Clinical Practices (ICH-GCP) principles, training of investigators, monitors, study co-coordinators in terms of conducting this trial:

- 6.4 Detailed monitoring plan for each site: [Attach as an appendix if necessary]
- 6.5 Details of trial insurance: [e.g. insurer, policy holder, policy number, insurance cover, period of validity]
- 6.6 Details of possible conflict of interest of any person(s)/organization(s) who/which will be involved in the trial:
- 6.7 Remuneration to be received by investigators, trial participants or others: [Indicate breakdown of costs to be covered, if applicable. Indicate compensation to be received by participants for travel and incidental expenses.]

SECTION 4: DECLARATION BY APPLICANT

| | |
|--|-------------------|
| Title of the Study: | |
| Protocol No: | |
| Version No: | Date of Protocol: |
| Study investigational medicinal product: | |

I/We, the undersigned has/have submitted all requested and required documentation, and have disclosed all information which may influence the approval of this application.

I/We, hereby declare that all information contained in, or referenced by, this application is complete and accurate and is not false or misleading.

I/We, agree to ensure that if the above said clinical trial is approved, it will be conducted according to the submitted protocol and all applicable legal, ethical and regulatory requirements.

| | |
|--|-------|
| _____ | _____ |
| Applicant | Date |
| _____ | _____ |
| Principal Investigator | Date |
| _____ | _____ |
| Coordinator/Other (State designation) | Date |

SECOND SCHEDULE

Made under regulation 4(1)(h)

DECLARATION BY PRINCIPAL INVESTIGATOR

Name:
Title of the study:
Protocol and site:

I, the undersigned, declare that:

1. I am familiar with the International Conference on Harmonization-Good Clinical Practice (ICH-GCP) principles and understand the responsibilities and obligations of the Principal Investigator (PI) within the context of this study.
2. I have notified the Tanzania Food and Drugs Authority (TFDA) of any aspects of the study with which I do not/am unable to, comply. (If applicable, this may be attached to this declaration.)
3. I have thoroughly read, understood, and critically analyzed the protocol and all applicable accompanying documentation, including the investigator's brochure, patient information leaflet(s) and informed consent form(s).
4. I will conduct the trial as specified in the protocol and in accordance with TFDA requirements and ICH GCP principles.
5. To the best of my knowledge, I have the potential, at the site(s) I am responsible for, to recruit the required number of suitable participants within the stipulated time.
6. I will not commence the trial until written authorizations from the National Ethics Committee and TFDA have been obtained.
7. I will obtain informed consent from all participants or if they are not legally competent, from their legal representatives.
8. I will ensure that every participant (or other involved persons), shall at all times be treated in a dignified manner and with respect.
9. Using the broad definition of conflict of interest below, I declare that I have no financial or personal relationship(s) which may inappropriately influence me in carrying out this clinical trial. [*Conflict of interest exists when an investigator (or the investigator's institution), has financial or personal associations with other persons or organizations that may inappropriately influence (bias) his or her actions*].
10. I have*/have not (delete as applicable) previously been the principal investigator at a site which has been closed due to failure to comply with ICH-GCP.
11. I have*/have not (delete as applicable) previously been involved in a trial which has been closed as a result of unethical practices.
12. I will submit all required reports within the stipulated time-frames.

Tanzania Food, Drugs And Cosmetics (Clinical Trials Control)

G.N. No. 53 (contd.)

Signature: í í í í í í í í í í í ..
í í í í í í í í í í í .

Date:

Witness: (Sponsor): í í í í í í í ..
í í í í í í í í í í í

Date:

*Attach details

THIRD SCHEDULE

Made under regulation 4(1)(i)

DECLARATION BY MONITOR

Name:

Title of the study:

Protocol number:

Site:

I, the undersigned, declare that:

1. I am familiar with the International Conference on Harmonization-Good Clinical Practice (ICH - GCP) principles and understand the responsibilities and obligations of the clinical trial monitor within the context of this study.
2. I have notified TFDA of any aspects of the above with which I do not/am unable to, comply. (If applicable, this may be attached to this declaration.)
3. I will carry out my responsibilities as specified in the trial protocol and in accordance with TFDA requirements and ICH⁶GCP.
4. I declare that I have no financial or personal relationship(s) which may inappropriately influence me in monitoring this clinical trial.
5. I have*/have not (delete as applicable) previously been the monitor at a site which has been closed due to failure to comply with GCP.
6. I have*/have not (delete as applicable) previously been involved in a trial which has been closed as a result of unethical practices..
7. I will submit all required reports when needed.

Signature: í í í í í í í í í í í .. Date:
í í í í í í í í í í í í

Witness:(Sponsor) í í í í í í í í .. Date:

*Attach details

FOURTH SCHEDULE

Made under regulation 5 (1) (j)

JOINT DECLARATION BY SPONSOR (OR REPRESENTATIVE) AND PRINCIPAL
INVESTIGATOR CONCERNING SUFFICIENT FUNDS TO COMPLETE STUDY

Title of the study:

Protocol:

I, <full name>, representing <Sponsor or representative>

and

I, <full name>, Principal Investigator

hereby declare that sufficient funds have been made available to complete the above-mentioned study.

Signed

Date

SPONSOR (or representative)

Name

Address

Contact details

Signed

Date

PRINCIPAL INVESTIGATOR

Name

Address

Contact details

FIFTH SCHEDULE

Made under regulation 6(3)

APPLICATION FOR CLINICAL TRIAL PROTOCOL AMENDMENT

APPLICATION FOR APPROVAL OF:

- PROTOCOL AMENDMENT
- INCREASE IN NUMBER OF STUDY PARTICIPANTS
- CHANGES IN DOSE/REGIMEN OF INVESTIGATIONAL MEDICINAL PRODUCT

Title of the study:

Protocol Number:

Date:

1. APPLICANT
 - 1.1 Name
 - 1.2 Address
 - 1.3 Telephone
 - 1.4 Fax number
 - 1.5 Email address
2. TRIAL PARTICULARS (original application)
 - 2.1 Trial Approval Number:
 - 2.2 Date of Approval of original protocol:
 - 2.3 Principal Investigator(s) approved for this trial:
 - 2.4 Number of local sites approved for this trial:
 - 2.5 Number of participants approved for this trial:
3. AMENDMENT PARTICULARS
(Please list requests for approval)
 - 3.1 Does the applicant wish to increase the number of local study participants participating in this trial?
Yes
No
 - 3.2 Does the applicant wish to change the dose/regimen of the investigational medicinal product?
Yes
No
 - 3.3 Does this amendment request require a new consent form to be signed by the participant?
Yes
No

If Yes please submit new PIL together with this application.

Protocol Amendment Number:

Version Number and Date of Protocol Amendment (for each document submitted):

General motivation for the proposed amendment: [List all of the issues included in the amendment and provide the rationale for each amendment]

Details of the proposed protocol amendment: [For each amendment, provide reasons for amendment and clearly highlight changes to the original protocol; this can be done either as old text replaced with new text or with the old text deleted with a line through it and the new text in bold and underlined]

3.4 Will this amendment apply to all approved site(s)?

Yes

No

If No: Specify the investigator(s)/site(s) for which the amendment will apply:

4. ETHICS COMMITTEE APPROVAL

4.1 Have the Research Ethics Committee(s) responsible for each centre to which this amendment applies been notified?

4.2 Research Ethics Committee(s) responsible:

4.3 Date of application to Ethics Committee:

4.4 Date of approval by Ethics Committee:

I/We, the undersigned, agree to conduct/manage the above-mentioned trial under the conditions as stated in this application. (The person(s) undertaking legal responsibility should sign this form).

Applicant

Date

SIXTH SCHEDULE

Made under regulation 4(3)

APPLICATION FOR ADDITIONAL INVESTIGATOR(S), CHANGE OF
INVESTIGATOR(S) OR ADDITIONAL CLINICAL TRIAL
SITE(S)

APPLICATION FOR APPROVAL OF:

- CHANGES IN INVESTIGATOR(S) AT APPROVED SITE (includes
additional investigators)
- ADDITIONAL SITE(S)

Title of the study:

Protocol number:

Date:

1. APPLICANT

- 1.1 Name
1.2 Address
1.3 Telephone
1.4 Fax number
1.5 Email address

2. TRIAL PARTICULARS (original application)

- 2.1 Trial approval number:
2.2 Date of approval of original protocol:
2.3 Principal investigator(s) approved for this trial:
2.4 Number of local sites approved for this trial:
2.5 Number of participants approved for this trial:

3. INVESTIGATOR'S DETAILS

- 3.1 Name and address of additional Investigator(s)/Changes to Investigators: [Proof of ICH - GCP training shall be provided for investigators who have not previously participated in clinical trials]

Tanzania Food, Drugs And Cosmetics (Clinical Trials Control)

G.N. No. 53 (contd.)

3.2 Summarise other ongoing/planned studies at the site involving the investigator:
[Provide details of studies, including numbers of study participants, whether the investigator is involved in research in a full-time or part-time capacity, and any other details that may affect the capacity of the site at any one time]

3.3 Date of application to Ethics Committee:

3.4 Date of approval by Ethics Committee:

3.5 Is CV for additional investigator(s) attached?

Yes

No

3.6 Is the declaration of Intent attached?

Yes

No

(If yes, attach declaration)

4. CAPACITY OF THE SITE

Describe how the site is structured so as to be able to take on the work for which this application is being made: [Give details of support staff, facilities, back up and any other relevant infrastructure].

5. RATIONALE FOR APPLICATION

5.1 Briefly explain the reason for the new investigator/s or site(s):

I/We, the undersigned, agree to conduct/manage the above-mentioned trial under the conditions as stated in this application. (The person(s) undertaking legal responsibility should sign this form).

Applicant

Date

| |
|--|
| Full Name:í . |
| Signature:í .. |
| Dated _____ at _____ :í í í í í í í í í í .thisí í í í í .day ofí í í í í í í í ..201í í í .. |

4. Payment (For official use only)

| |
|--|
| Amount of fine to be paid:í í í í í í í í í í í í í í í í í í .. |
| Name and signature of Authorized officer:í í í í í í í í í .. |
| Name and signature of cashier:í í í í í í í í ..í í í í í .í |
| Receipt number:í í í í í í í í í í í í í í í í í í í |
| Date and stamp:í |
| NB: Cashier should attach copy of receipt |

Dar es Salaam,
í í í í í í í í , 2013

HUSSEIN A. MWINYI
Minister for Health and Social Welfare