

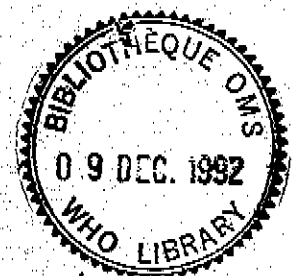


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REGISTRATION OF PHARMACEUTICALS TANZANIA



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Extracts from a report on the Pharmacy Board in Tanzania

by

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I. INTRODUCTION

The text which follows is extracted from a report prepared by Mrs G. Kristinsdottir, Secretary General of the Committee on Pharmaceuticals (Lyfjanefnd, Iceland), consultant for the Action Programme on Essential Drugs, after a visit to the United Republic of Tanzania. Because of the quality of the recommendations and their applicability to many national situations, it was decided to widely disseminate the most relevant parts of this document.

II. REGISTRATION OF PHARMACEUTICALS

Important aspects of pharmaceutical registration which should be explicitly stipulated in the Act are the following:

1. The term pharmaceutical has to be clearly defined in the Act. It is judicious that the definition covers a broad sphere and has provisions for exemptions therefrom, which can be made by regulations (example: several vitamins, which can be classified as food additives). The definition should cover both pharmaceuticals intended for human and for veterinary use.
2. Provision concerning pharmaceuticals, namely that a pharmaceutical may not be imported, sold or distributed in Tanzania unless an application for registration of the product in question has been submitted by the manufacturer to the Pharmacy Board's Secretariat and such an application has been approved by the Minister of Health on recommendation of the Board.
3. Provision that an approval for registration of a pharmaceutical is only granted based on evaluation of quality, safety and efficacy as well as on the need for it in the country.
4. It should be specified in the Act which pharmacopoeia or pharmacopoeias are applicable or in force in the country.
5. Provision that the Minister of Health can on recommendation from the Board grant exemptions for importation of unregistered pharmaceuticals, if special reasons arise (as for use in clinical trials, in emergency situations).
6. Provision that the Minister of Health can on recommendation from the Board confine the registration of a pharmaceutical to sole use in special wards of hospitals and/or prescriptions of specialists in individual branches of medicine.
7. Provision that it is permissible to reject an application for registration of a pharmaceutical, if the active ingredient is so similar to an available pharmaceutical already registered that the difference can not be of importance (a need clause - based on these provisions the authority can limit numbers of similar substances within a therapeutic group).

It should also be stated in the text that in case of rejection the application fee is not reimbursed.

8. Provision that the Board can request supplementary information and documentation concerning an application for registration as well as for an already registered pharmaceutical if considered necessary. The manufacturers should also be obliged to provide the Board with any new information pertaining to registered pharmaceuticals and those in the process of registration, as soon as possible.

9. Provision that the Pharmacy Board be permitted to call on specialists and representatives of associations of specialists to act in an advisory capacity whenever deemed necessary.
10. Provision that the registration of a pharmaceutical can be cancelled if:
 - the registration was obtained on the basis of fraudulent or inaccurate information;
 - the circumstances in which the pharmaceutical was registered no longer exist;
 - the conditions under which the pharmaceutical was registered have been contravened;
 - it is in the public interest to cancel or suspend the registration.
11. Provision that conditions for registered pharmaceuticals may be revised.
12. Provision that a batch of a registered pharmaceutical may be recalled if the standard of identity, strength, quality and purity prescribed in the documentation for registration are not met.
13. Provision that the manufacturer who applies for registration of a pharmaceutical has to comply with the WHO Standards of Good Manufacturing Practices (GMP), rules and other regulations as may be determined by the Board.
14. Provision that the Minister of Health can on recommendation from the Board classify pharmaceuticals into various dispensing groups (prescription only, non-prescription (OTC), controlled drugs).
15. Provision on minimum requirements of labelling of pharmaceuticals as follows:
 - name of the pharmaceutical;
 - dosage form;
 - active ingredient(s), given by INN, if available and its (their) quantity(ties) in each measured unit of the dosage form (e.g. tablets, capsules, amount/ml of injections etc.);
 - the number of measured units of the dosage form concerned (e.g. number of tablets, capsules or ampoules etc.) or the total quantity of the preparation in weight or volumetric measure units;
 - production number which shall indicate the production batch so that its origin can be easily traced;
 - name and address of the manufacturer;
 - storage conditions and shelf-life by month and year (it shall not be given as a code).

Further requirements of labelling may be prescribed by the Minister of Health on recommendation from the Board by regulations.

16. Provision that advertisement and promotion of registered pharmaceuticals shall be in conformity with the conditions laid down by the approval of registration of the product in question.
17. Provision that free samples of pharmaceuticals to the general public for advertisement and/or promotional purposes should be prohibited.
18. Provision that the Board be authorized to forbid advertisements relating to surgical or medicinal instruments or pharmaceuticals which give incorrect or misleading information as well as to forbid advertisement of special pharmaceuticals to the public.

19. Provision about the duration of granted registration of a pharmaceutical and the required time for submission for renewal of registration; application for renewal should be lodged 6 months prior to the expiry of existing registration.
20. Provision that the Pharmacy Board be obliged to:
 - publish a register of approved pharmaceuticals containing information about approved modes of application/usage (data sheet);
 - convey, by means deemed appropriate, information about drugs which have ceased to be registered.
21. Clinical trials should be defined in the Act and followed up by regulations.
22. Provision that the members of the Pharmacy Board, its sub-committees and personnel of the Board's Secretariat be subject to confidentiality regarding all information in course of their duties and which relates to the special assessment of individual pharmaceuticals unless they are by Law duty bound to express themselves.

III. THE PROCEDURE OF PHARMACEUTICALS' REGISTRATION

1. The first step in the registration procedure of pharmaceuticals is to state the basic requirements needed for the registration. This has already been done by approval of the National Drug Policy (NDP) for Tanzania. Subsequently it has to be followed by updating the present legislation (The Pharmaceuticals and Poisons Act 1978 and the Regulations from 1990) as previously pointed out.
2. The second step is to licence persons and premises which are involved. Such licensing is already accomplished in the country (pharmacists, manufacturers, importers, wholesalers, distributors).
3. All local manufacturers and importers (which are known since they have to be licenced) as well as the Central Medical Stores (CMS) should be asked to supplement a list to the Pharmacy Board Secretariat, within a given period of time, containing all pharmaceuticals they have either produced or imported into the country within the last year. For each drug they should indicate the main therapeutic group to which it belongs.

Then a notice should be given through the Government Gazette or by other suitable means that all manufacturers and importing agencies have to notify the Board on standardized notification forms of all pharmaceuticals they intend to continue to manufacture or import into the country.

Since it would be very difficult if not impossible to accept at the same time notifications of all categories of pharmaceuticals the notifications should preferably be invited at intervals, as the Board may decide, and in groups according to therapeutic classification starting with the most important or most widely used ones and so on until all therapeutic groups are covered.

A period of for example 6 months after the date fixed for submission of notification for each therapeutic group should be given in order to avoid interruption of supply. It is also desirable to evaluate all notifications of products classified within the same therapeutic group jointly to gain a better view of products available on the market.

It should be stated that, after a stipulated date, distribution, sale and importation of pharmaceuticals other than those which have been notified to the Secretariat will be prohibited, unless the Secretariat (Board) has granted a specific licence thereof (pharmaceuticals not previously on the market).

Each notification of a pharmaceutical already on the market shall be sent on request to the Board's Secretariat using a special standardized notification form, prepared by the Secretariat.

The notification form, prepared by the registration unit of the Secretariat, should include the following details:

- Name of the pharmaceutical (either generic or brand name) and the main therapeutic group.
- Name of active ingredient(s) given by INN (International Nonproprietary Name), if available.
- Dosage form, strength and route of administration.
- Manufacturer, name and full address (business address, postbox, telephone and telefax, if available).
- Manufacturing country.
- Importing agent, name and full address (business address, postbox, telephone and telefax, if available).
- Complete composition of the pharmaceutical, active ingredient(s) (under INN) in mg (or per cent).
- Therapeutic indications.
- Package sizes and prices.
- Copy of all labelling, including any package insert.
- Remarks (space for remarks for the applicant).
- The manufacturer shall provide an approved data sheet for the product from the country of origin.

If the manufacturer or importer (distributor) does not complete the required form for the pharmaceutical supplied, the Board may cease the sale of the product after a fixed date.

All pharmaceuticals within a therapeutic group notified to the Board's Secretariat shall be licensed to be on sale for a specified time, for example 1-2 years. A special form for temporary marketing (licence) should be prepared by the Secretariat which shall be completed by the Registrar and issued at the receipt of each notification. Within the time limit mentioned above, the manufacturer shall officially apply for registration of the pharmaceutical by a formal application for registration (see later).

4. Administrative filing of notifications (and applications later on):

Each notification of a pharmaceutical submitted to the Secretariat shall be given a file number in chronological order according to its receipt [e.g. the first one received in the year 1992 would be given the file number 92001 (the first two numbers referring to the year of receipt); the 29th would be given the file number 92029, and so on]. These file numbers could be used as registration numbers and as reference numbers in all correspondence. The staff (pharmacists) at the Secretariat's registration unit shall in the beginning file each notification and prepare card indexes for each product in the following manner:

(a) NAME INDEX

In alphabetical order by the name of the pharmaceutical (whether a generic or a brand name).

Information on the card:

- Trade name of the product
- Manufacturer
- Importer
- Notification number
- Active ingredient(s), dosage form and strength.

(b) ACTIVE INGREDIENT INDEX

In alphabetical order by the active ingredient(s) (INN).

Information on the card:

- Trade name of the product
- Manufacturer
- Importer
- Notification number
- Active ingredient(s), dosage form and strength.

In case of a pharmaceutical containing a combination of two or more active ingredients the product should be listed in this card-index according to each active ingredient and it should be stated as well on the cards that this is a combination. (Thus a combination of 3 different active ingredients will be listed on 3 different cards).

(c) THERAPEUTIC CLASSIFICATION INDEX

A card index of therapeutic classification (main indication) of the pharmaceutical (according to the therapeutic classification system which will be used).

Information on the card:

- Therapeutic group
- Trade name of the product
- Manufacturer
- Importer
- Notification number
- Active ingredient(s), dosage form and strength.

(d) MANUFACTURER INDEX

In alphabetical order by the manufacturer.

Information on the card:

- Trade name of the product
- Manufacturer
- Importer
- Notification number
- Active ingredient(s), dosage form and strength.

Besides those four types of card-indexes a filing cabinet (or hanging folder file) should be set up for records (documents) for both notification and registration (see later) purposes:

- Arranged after notification/registration/application number; the forms themselves, summary of documentation (kept in below mentioned system), all correspondence as well as licensing (registration) approval or rejection.
- Then there is a need for another supplementary documentation system, arranged after registration/application numbers for supporting documentation and even documents received with the original application. Probably the cheapest way is to keep these documents on shelves (wall shelves).

It should be mentioned that all documents supplied by the applicant are matters of confidentiality and should be stored in accordance thereto.

In the future, when the registration process of pharmaceuticals is started three more types of card-indexes would be convenient:

- A card-index for products approved registration (in alphabetical order after the trade name of the product).
- A card-index for products rejected registration (in alphabetical order after the trade name of the product).
- A card-index for products withdrawn from the market (either by the manufacturer or the authority) in alphabetical order according to the trade name of the product.

Cards for these three card-indexes should consist of those previously filed in the card-index filed in alphabetical order by trade names (see proposal of card-indexes). When cards are removed from the original card-index into the approved-, rejected- or withdrawal-indexes, the action and the date of action taken should be added on the relevant cards.

The Board has to undertake at the earliest opportunity a review of all received notifications on pharmaceuticals in each specified therapeutic group to secure the withdrawal of any product which on the basis of a review of its ingredients and indications is judged not to meet required standards of safety.

This might be done by cancelling a previously granted temporary marketing license.

5. After finishing the notification procedure a gradual start should be made with the official registration procedure.

As mentioned before the manufacturer or distributor of a pharmaceutical with a temporary marketing licence should be obliged to apply for a formal registration of the product within a fixed time limit (before the end of expiry date of temporary granted marketing licence), conceivably two months earlier.

An application form for registration of a pharmaceutical is already available at the Board's Secretariat (registration unit), (named: Application for registration of a drug). (Sec Annex I).

The format of this application form is quite acceptable.

The following comments and advice should be considered:

- The permanent address of the Pharmacy Board Secretariat should be added. (Reason: the application documents may be too bulky for an ordinary postbox and it is often undesirable to send samples through a postbox).
- It would be desirable to add the applicant's postbox and telefax number if available. Furthermore, the applicant's address should be given in the same manner as for the manufacturer (ref. application form).
- It would be desirable to add the manufacturers telefax number if available.
- In item D on the application form the declaration of the product is to be given.

It would be desirable just to state there, that the complete composition of the product shall be given on a special composition scheme accompanying the application form. In the composition scheme the following details should be enumerated:

- The names of both active ingredient(s) and other constituents (auxiliary substances) written under INN (International Nonproprietary Name), when available (references should be given).
- The quantity of each ingredient both active and inactive per unit (tablet, capsule, ml, g).
- Standard of ingredient (i.e. BP, USP, etc.)
- Function of each ingredient:
 - A: Active ingredient
 - I: Inactive substance, which is not grouped elsewhere
 - C: Colouring agent, always identified by Colour Index number (CI)
 - P: Preservative
 - AO: Antioxidant
 - S: Stabilizer
 - F: Flavouring agent
 - AP: Aerosol propellant.

These suggestions are made bearing in mind the planned future computerization of the Board's documentation needs and in order to prepare for and facilitate its implementation. (See Annex II).

- Information about the therapeutic category (group) for the product should be added.
- On the application form the applicant is not asked to give information about the price of the product. If the Board decides to take the price of the products into consideration and uses a high price as a reason for rejection of registration, price information must be given by the applicant.

These provisions are in line with the National Drug Policy.

- In item D of the application form information about registration in other countries (pending or approved) shall be stated. It would be advisable to add "withdrawn or rejected" and also reasons for withdrawal or rejection.
- In item J on the application form (Enclosures) "package insert" should be added as well as proposal for "Data Sheet" for the product.
- Under the "Board's records only", item 12 should read as follows: "Accepted package size(s) and price(s) (max)" if the Board is going to deal with prices (eventually max. price).

A formal application for registration of a pharmaceutical shall be submitted to the Pharmacy Board's Secretariat. The application form shall be completed properly in duplicate together with a completed composition scheme and accompanied by the application fee.

The Registrar shall sign both copies of the application form and return one of them to the applicant.

A distinct application should be submitted for each separate preparation form (dosage form, different strengths).

IV. REQUIRED DOCUMENTATION, WHICH SHOULD BE SUBMITTED WITH EACH APPLICATION

Each manufacturer has to provide evidence of compliance with the WHO standard of Good Manufacturing Practices (GMP), rules and other requirements as may be determined by the regulatory authority.

The inspection unit should give the registration unit and the Committee on Medicines advice concerning approval of manufacturers (GMP Certificates).

Foreign manufacturers should submit certificates of registration of their products in other countries (including country of origin) and the data sheets of those products approved in those countries.

1. Known active ingredient

For products containing known, well established active ingredients the following elements of information should accompany an application for registration (most of this is already part of the application form):

- name of the product
- active ingredient(s) (INN)
- dosage form
- therapeutic classification (category)
- complete (quantitative) formula of the dosage form (incl. excipients)
- quality control specifications (description of analytical methods)
- indications, dosage, method of use
- contraindications, warnings, precautions
- bioavailability data (in vitro/in vivo)

- stability data (results from at least two or 3 batches), shelf-life and storage conditions
- container, packing, labelling
- proposed sales category (prescription only, OTC, controlled preparation, pharmacy sale, general sale)
- importer/distributor.

References to authorized and other approved pharmacopoeias may be used (both for active and inactive ingredients), but the manufacturer must prove that his own specifications are at least equivalent to the quality standards of referred pharmacopoeia.

If the dosage form is a novel one (such as a slow release tablet) or if a new route of administration is proposed, further information from clinical studies will or may be required.

2. New active ingredient

For products containing new chemical entities considerably more extensive information is required than for a well known chemical entity in order to provide assurance of efficacy and safety as well as of quality i.e.:

(a) CHEMICAL AND PHARMACEUTICAL DATA

- name of the therapeutically active substance(s) (generic name(s) INN if available);
- structural formula, molecular formula and chemical name, physical properties, synthesis, specifications, impurities, stability characteristics;
- chemical relationship to other substances;
- quality specifications of all other ingredients than the active one(s) should be given, including flavours, colours, propellants; substances that disappear partly or completely during manufacture should be stated;
- detailed information regarding the methods of analysis or tests in connection with:
 - * the identification and quantitative estimation of the preparation;
 - * purity;
 - * stability (data from at least two or three batches analysis);
 - * certificate of analysis.

(b) TOXICOLOGICAL AND PHARMACOLOGICAL DOCUMENTS

These documents should be submitted in a summary form and the regulatory authority can demand complete reports or other supplementary information. The information in the summary must be given with references to the original reports in a reference list which shall be attached (published papers, manuscripts and laboratory reports).

There should be the following headings in the summary:

Introduction of the pharmaceutical, single dose toxicity, repeated dose toxicity, reproduction studies, mutagen potential, carcinogenic potential, pharmacodynamics (including mode of action), pharmacokinetics (absorption, distribution, excretion).

(c) CLINICAL DOCUMENTS

These documents should be submitted in a summary form and the regulatory authority can demand complete reports or other supplementary documentation. The information in the summary must be given with references to the original reports in a reference list which shall be attached.

The summary must present the properties, indications, advantages and disadvantages of the pharmaceutical in comparison with other well-known product(s) with the same indications.

The following should be the headings for the summary:

Introduction of the pharmaceutical, therapeutic efficacy, adverse reactions, interactions, toxicity, abuse liability, special precautions (as use during pregnancy, breastfeeding, in children, elderly patients and patients with complicating diseases such as liver and kidney diseases, overdose, intoxication).

In case of a new chemical entity it is advisable to wait with registration of such products until a multidisciplinary assessment has been performed by another or other highly evolved regulatory authorities or to monitor their performance in use through postmarketing surveillance.

In the case of products containing a new chemical entity, intended exclusively for tropical diseases, the expertise of the WHO is at hand to offer advice in these cases and this should be sought.

Registration of combinations of potent, therapeutically active substances should not be granted unless they have been thoroughly investigated that there are evident advantages to use the substances together rather than individually.

All documents with an application for registration of a pharmaceutical should be submitted in duplicate and with samples of the product itself.

In case of application for renewal of registration of a pharmaceutical the manufacturer should be allowed to refer to earlier submitted documentation and information on the product.

In the Regulations 1990, Part II, sub-section (5) of Section 3 the applicant of a registered pharmaceutical is supposed to inform the Board of any change of the product within fourteen days from the date of such change.

This procedure has to be altered. The applicant (manufacturer) should be obliged to apply formally for approval of change of the composition of a registered pharmaceutical in advance and should not be allowed to put the new composition on the market before approval. The applicant should not be charged a fee for such applications.

V. THE COMMITTEE ON MEDICINES

The Committee on Medicines (as it is named in the draft of new Act) is an advisory committee to the Board on matters relating to registration of pharmaceuticals and cancellation or suspending of such registration, based on evaluation of quality, safety and efficacy and usefulness of the pharmaceuticals.

Considering the functional responsibility of the Committee it should consist of persons with the widest possible education, knowledge and experience in the fields of pharmacy, medicine and pharmacology, such as pharmaceutical chemistry, pharmaceutical formulation, internal medicine, toxicology and clinical pharmacology.

The Board should be represented on the Committee on Medicines by one of its members, in order to secure proper coordination and dissemination of relevant information between the two bodies.

Bearing in mind the linkages between the two bodies and the fact that the Committee's Chairman has a primary responsibility for its activities, it is advisable that the Board's representative assumes the Chairmanship.

The senior pharmacist in the registration unit should be appointed the Committee's Secretary due to the fact that daily involvement with registration issues should make the person well conversant with all matters being submitted to the unit.

The Committee on Medicines should on behalf of the Board be granted the authority to:

- request more detailed information or documentation if considered necessary to ensure the quality, efficacy and/or safety of the product;
- seek the opinion or assistance of specialists in the various medical or pharmaceutical disciplines if it considers the need for that.

As said before, the primary role of the Committee on Medicines is to function in an advisory capacity to the Board on matters related to registration of pharmaceuticals. The Committee's members, based on their area of specialization, have to assess the documentation accompanying each application for registration and prepare and submit to the Board a brief appraisal concerning pharmaceutical data, pharmacological and toxicological data and clinical data.

A proposed drug data sheet should be prepared in collaboration with both the registration unit and the information unit and contain and cover the following details as far as possible:

- Name of the pharmaceutical.
- Manufacturer.
- Dosage form and route of administration.
- Therapeutic classification.
- Active ingredient(s) and strength.
- Properties of the product (description of the active ingredient(s), mode of action (absorption, distribution, excretion). If the product contains several substances, the effect and mode of action may be described separately for each substance.
- Indication(s).
- Contraindications.
- Adverse reactions (side effects: should preferably be listed as "most frequent (>1/100)", "less frequent (1/100 - 1/1000)" and "rare (<1/1000)").
- Interactions.
- Overdosage, treatment of intoxications.
- Precautions and warnings (pregnancy, breastfeeding, patients with complicated diseases as reduced liver- and kidney function).
- Dosages (dosage for children or elderly should be mentioned if available).
- It should be stated if the product is not intended for usage by children.
- Storage instructions and shelf-life.
- Package sizes (including description) and prices.
- Sales category (prescription only, non-prescription, narcotic, special controlled product, etc.).
- Proposal for duration of registration.
- Proposal for approval of package insert.
- Other proposals (as hospital use only, prescription only by specified specialists of medicine, special demands of labelling or usage instructions to ensure the right use of the product, etc.).

NOTE:

If the product is to be included in the National Formulary, the approved drug data sheet should be used as a basis.

The Secretary of the Committee on Medicines shall prepare submissions to the Board in accordance with the Committee's deliberations and recommendations.

Subsequent to the final assessment of the application for registration of any pharmaceutical the Ministry of Health shall send the applicant a formal notice of approval or rejection, whichever the case may be.

In case of approval the applicant should receive a detailed listing of the approved data sheet and other relevant aspects contained in the Pharmacy Board's submission to the Ministry, concerning the registration of the pharmaceutical (including the registration number, which may be equal to application number).

If application for registration is rejected the reasons for the rejection should always be given to the applicant.

Pharmaceuticals obtained by means of tendering or donations should be granted a status of temporary registration, lasting for one year. Requirements for temporary registration have to be set by the Committee on Medicines.

The Committee on Medicines should on behalf of the Board appraise clinical trials which should only be allowed when they are essential for some reason in Tanzania.

The Board should in cooperation with the Committee on Medicines specify conditions for clinical trials.

* * *

ANNEX I

THE UNITED REPUBLIC OF TANZANIA
THE PHARMACY BOARD

BPF _____

"THE PHARMACEUTICALS AND POISONS REGULATION, 1990"**APPLICATION FOR REGISTRATION OF A DRUG**

To be sent to the Registrar, Pharmacy Board, P.O. Box 9083, Dar es-Salaam, Tanzania.

A. Particulars of applicant

Name	Telephone and telex
Address	

B. Manufacturer's particulars

Name	Telephone and telex
Address (street, P.O. Box, city, country)	

C. Product particulars

Name (trade and INN-name)	
Formulation	Strength

D. Declaration

Name and quantity of active ingredients and constituents; the names should be written under the international nonproprietary name, where available.

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OFFICIAL DESIGNATION AND PROFESSIONAL STATUS OF TECHNICAL MANAGER

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Applicant's signature:..... Date:

E. Legal category requested

Prescription	General sales
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F. Indication and dosage schedules

Recommended clinical indications and routes of administration

Recommended doses and dosage schedules

Contraindications, precautions and warnings listed

G. Registration in other countries (pending or approved)

	Sales category (prescription/OTC)

H. Proposed sales category

Prescription	Yes <input type="checkbox"/>
OTC	No <input type="checkbox"/>

I. Package size

--

J. Enclosures

Labelling material	<input type="checkbox"/>
Pharmaceutical documentation	<input type="checkbox"/>
Pharmacological documentation	<input type="checkbox"/>
Clinical documentation	<input type="checkbox"/>
Sample	<input type="checkbox"/>
Complete WHO certificate of product from country of origin	<input type="checkbox"/>

BOARD'S RECORDS ONLY

1. Application No:
2. Date of receipt:
3. Application fee:
4. Essential drug:
5. Accepted indication:
6. Prescription status:

OTC	<input type="checkbox"/>
Prescription only	<input type="checkbox"/>

7. Therapeutic value:

Vital	<input type="checkbox"/>
Essential	<input type="checkbox"/>
Non essential	<input type="checkbox"/>

8. Refused (date):
9. Postponed (date):
10. Conditionally approved (date):
11. Final approval (date):
12. Accepted package size:

Special conditions:

