



BADAN PENGAWAS OBAT DAN MAKANAN
REPUBLIK INDONESIA

**DECREE OF
THE HEAD OF NATIONAL AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA
NUMBER : HK.00.05.3.1950**

ON

CRITERIA AND PROCEDURE OF DRUG REGISTRATION

**THE HEAD OF NATIONAL AGENCY OF DUG AND FOOD CONTROL
REPUBLIC OF INDONESIA**

- Considering** :
- a. that in order to protect the public from the drug that do not fulfill the criteria of drug efficacy. Safety, quality and public health need, it is necessary to execute drug evaluation under the regulation of drug registration prior to marketing.
 - b. that several provision in drug regulation were no longer suitable with the development of science and technology, therefore it is necessary to review and to re-regulate the procedures of drug registration and evaluation;
 - c. that in the framework of entering the era of globalization and harmonization in the pharmaceutical field, the regulation of drug registration must be improved;
 - d. that based on the consideration as referred to item a, b and c, it is necessary to stipulate the Decree of the Head of the National Agency of Drug and Food Control, the Republic of Indonesia, upon the Criteria and the Procedure of Drug Registration.
- In View of** :
1. The law on Prescription Drugs (State Gazette of 1949 No. 419);
 2. Law Number 23 of 1992 on Health (State Gazette of 1992 Number 100, Supplement to State Gazette Number 3671);
 3. Law Number 5 of 1997 on Psychotropics (State gazette of 1997 Number 10, Supplement to State Gazette Number 3671).
 4. Law Number 22 of 1997 on Narcotics (State Gazette of 1997 Number 67, Supplement to State Gazette Number 3698)
 5. Law Number 8 of 1999 on Consumer Protection (State Gazette of 1999 Number 42, Supplement to State Gazette Number 3821).



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6. Government Regulation Number 17 of 2001 on Tariff of Non-Taxes of State Income applied in the National Agency of Drug and Food Control.
7. Presidential Decree Number 103 of 2001 on Position, Task, Function, Authority, Organizational Structure and Activity of Non Departmental Government Institution as amended by the Presidential Decree of 2002 Number 46.
8. Presidential Decree Number 110 of 2001 on Unit of Organization and the Task of First Echelon State employees of Non Departmental Government Institution as amended by Presidential Decree Number 48 of 2002.
9. Regulation of the Minister of Health Number 949/MENKES/PER/VI/2000 of 2000 on Drug Registration.
10. Decree of the Head of National Agency of Drug and Food Control Number 02002/SK/KBOOM of 2001 on Organization, Task and Function of The National Agency of Drug and Food Control;
11. Decree of the Head of National Agency of Drug and Food Control Number 02002/SK/KBPOM of 2001 on Procedure of Clinical Trial;
12. Decree of the Head of National Agency of Drug and Food Control Number HK.00.05.3.00914 of 2002 on Special Access Scheme on Drugs.

DECIDES

To Stipulate : THE DECREE OF THE HEAD OF NATIONAL AGENCY OF DRUG AND FOOD CONTROL ON CRITERIA AND PROCEDURE OF DRUG REGISTRATION.

**CHAPTER 1
GENERAL PROVISION**

Article 1

In this Decree

1. **Registration** is a procedure of drug registration application and drug evaluation in order to obtain marketing authorization.
2. **Marketing Authorization** is an official approval on drug registration for the purpose of marketing a pharmaceutical product in Indonesia.



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3. **Therapeutic Products** are any preparations or combination of ingredients including drug, biological product and other preparations which are intended to modify or explore physiological system or pathological states for diagnosing, treatment, recovery and health improvement.
4. **Drug** is any pharmaceutical product including biological product which is composed of active ingredient, including contraceptives and other preparations containing medicine.
5. **Narcotic** is ingredient or drug derived from herbs or non herbal, either synthetic or non synthetic, which may inhibit or affect consciousness, induce anesthesia, alleviate to relieve pain.
6. **Psychotropic** is ingredient or drug, either natural or synthetic non-narcotics, which act psycho-active selectively affecting central nervous system which may induce specific changes to mental activities and behavior.
7. **Biological products** are vaccine, antibody, antigen, hormone, enzyme, blood product and other fermentation product (including monoclonal antibody and products derived from recombinant DNA technology) which are used to modify or explore physiological and health improvement).
8. **Contraceptives** are drugs or devices which are intended for prevention of conception.
9. **New drug** or **new finished drug** is a drug which new active ingredient or composition or dosage form/route of administration or indication or posology which has not been approved in Indonesia.
10. **Copy drug** or **finished “me too” drug** is a drug which contain same active ingredient to a registered drug.
11. **Domestically manufactured product** is a drug which is domestically manufactured and packaged by industry in Indonesia.
12. **Contracted drug** is drug which manufacturing is delegated to other pharmaceutical industry.
13. **License drug** is a drug which is manufactured under license.
14. **Imported drug** is drug which is manufactured by overseas pharmaceutical industry.
15. **Patent protected drug** is drug which has obtained patent protection based on valid Patent Law in Indonesia.
16. **Counterfeit drug** is drug which is produced by an unauthorized party, against the prevailing regulation or drug manufacturing using similar identity or labeling of other drug which has had a marketing authorization.
17. **Contracting party** is a pharmaceutical industry or other institution which has delegated a drug manufacturing activity based on a contract.



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18. **Contractor** is a pharmaceutical industry which has accepted a drug manufacturing project based on a contract.
19. **Licensing** is delegation of right and authorization to use the research and development related to the transfer of technology in manufacture, utilization of research and development on efficacy, safety, quality and the use of trade name and marketing of a drug.
20. **Labeling** is a complete information on drug, efficacy, safety, posology and other information which are considered important to be put on the label, brochure and carton of a drug packaging.
21. **Marketing** is all activities in drug distribution channels or delivery related to trade, non-trade or delivery service.
22. **Floppy disk** is specific formatted disk for drug registrations.
23. **Marketing authorization status document** is an official document on drug status in a country which is issued by the drug regulatory authority, such as Certificate of Free Sale (CFS) and Certificate of Pharmaceutical Product (CPP).
24. **FERO (Fasilitas Elektronik Registrasi Obat = Electronic Facility for Drug Registration)** is an electronic facility that support drug registration system in a harmonized way, mainly to access data monitoring and registration process.
25. **STINEL (Standar Informasi Elektronik = Electronic Information Standard)** is standard of a complete information on drug, efficacy, safety, posology, and other information that must be submitted in the form B₂6-12.
26. **Formula** is a qualitative and quantitative composition of active and inactive ingredient in a drug.
27. **Form** is a drug registration form.
28. **Drug strength** is the concentration of active Ingredient in a drug.
29. **Composition** is the qualitative and quantitative composition of active ingredient in a drug.
30. **Independent Assessment Report** is a critical summary and interpretation of the data, with conclusions, prepared by on behalf of the drug regulatory authority in the country of a marketed drug and the result is not based on evaluation result of other country.
31. **Applicant** is a pharmaceutical industry or a pharmaceutical wholesaler which has received a business license in compliance to the prevailing regulation.
32. **Unit pack** is a smallest pack with label in compliance to the regulation.
33. **Established evaluation system** is evaluation system which is conducted in stages, and with method of evaluation in compliance to international standard by team or independent committee, who is authorized in a country recognized as innovated country.



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34. **Variation** is a change to any aspect of therapeutic product including but not limited to a change to formulation, method and site of manufacture, specifications for finished product and ingredients, container, packaging, labeling, and product information.
35. **Active pharmaceutical ingredient (API)** is a compound that is intended to be used in the manufacture of a pharmaceutical product as a therapeutically active compound (ingredient).
36. **Inactive Ingredient/Excipient** is component of drugs that are meant as filter, solvent, coating, propellant and ingredient to enhance drug usage, forming, preservative or as coloring agent non pharmacologically effective.
37. **Blood product** is a product derived from the component of blood or other blood component.
38. **Blood Component** is a component which is physically isolated from other blood component.
39. **The Head of Agency** is the head of the National Agency of Drug and Food Control the Republic of Indonesia.

Article 2

- (1) Therapeutic product that has been marketed in the territory of Indonesia and/or aims to be exported, must have a marketing authorization.
- (2) In order to obtain a marketing authorization as meant in sub-article (1), the applicant should submit a registration application.

**CHAPTER II
DRUG CRITERIA**

Article 3

- (1) In obtaining drug marketing authorization, a drug should fulfill the below main criteria:
 - a. Convincing evidence of efficacy, and adequate safety, proven through pre-clinical and clinical trials or other proof in accordance with development in the relevant scientific knowledge.
 - b. Having quality that fulfils the criteria concerning the production process in accordance with Good Manufacturing Practice of (GMP/CPOB), specifications and method of analysis of all materials used in the finished product with proven documents.
 - c. Labeling must contains objective and complete information which must ensure, rational and safe use of drugs.



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- (2) Besides the criteria as meant in sub-article (1) other below criteria should also be fulfilled:
 - a. Specifically or new psychotropic should have superiority in efficacy and safety compared to the standard drug and other marketed drugs in Indonesia for the claimed indication.
 - b. Specific contraceptives applied or the National program and other drugs for other National program, that will be decided later, should perform a clinical trial in Indonesia.
 - c. In conformity with the public health need.
- (3) The criteria for the public health need and affordability of the society as meant in sub-article (2) letter c, is stipulated separately by the Head of Agency.

**CHAPTER III
APPLICANT**

First Part

Applicant of Domestically Manufactured Products

Article 4

- (1) Domestically manufactured products include domestically manufactured products, domestically manufactured products under license from overseas company and contracted drug.
- (2) Applicant of Domestically manufactured products and domestically manufactured product under license from overseas company as meant in sub-article (1) are pharmaceutical industry from license or at least a principle license for pharmaceutical industry from the Head of Agency or an approval from foreign capital investment board.
- (3) Pharmaceutical industry as meant in sub-article (1) has an obligation to fulfill the GMP (CPOB) criteria.
- (4) Applicant of Contracted drug as meant in sub-article (1) is a contracting party which is a pharmaceutical industry or other agency.
- (5) The provision on the criteria for other agency as contracting party as meant in sub article (4) is stipulated separately by the head of agency.



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**Second Part
Applicant of Imported Drugs
Article 5**

- (1) Applicant of imported drug is a domestic pharmaceutical industry or pharmaceutical wholesaler which has obtained a written appointment letter from an overseas pharmaceutical industry or product owner.
- (2) Overseas pharmaceutical industry as meant in sub-article (1) oblige to fulfill the GMP criteria which must be proven by appropriate documents or if it is deemed necessary to be inspected locally by an authorized GMP inspector.
- (3) Provision on the inspection procedure as meant in sub-article (2), is stipulated separately by the Head of Agency.

**Third Part
Applicant of Drug for Export Only
Article 6**

- (1) Applicant of drug for export only should be a pharmaceutical industry.
- (2) Drugs for export only as meant in sub-article (1) should fulfill the criteria as meant in Article (3), unless accompanied by a written approval from the destination country.

**Fourth Part
Applicant of Patent Protected Drug
Article 7**

- (1) Applicant of patented drugs in Indonesia is a domestic pharmaceutical industry as patent holder, or other pharmaceutical industry or pharmaceutical wholesaler which has obtained a patent transferred from the patent holder in line with the valid patent provision in Indonesia.
- (2) Patent ownership as meant in sub-article (1) should be proven with a patent certificate.
- (3) Patent transfer as meant in sub-article (1) should be proven by a proof of transfer in line with the valid provision.



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Fifth Part

Responsibility of the applicant

Article 8

- (1) The Applicant is responsible for
 - a. The completeness of the submitted documents.
 - b. The truth of all information which is stated in the registration documents.
 - c. The truth and validity of documents which are attached to support the registration.
 - d. Revisions and additional data and information on the product that is in the process of registration or has already had a marketing authorization.
- (2) Each revision as meant in sub-article 91) letter d should have an approval from the Head of Agency.

CHAPTER IV

CLASIFICATION AND CATEGORY OF DRUG REGISTRATION

First Part

Classification of Drug Registration

Article 9

- (1) Drug is classified into therapeutic class.
- (2) Therapeutic class as meant in sub-article (1) is based on the classification on Anatomical Therapeutic Chemical (ATC).

Second Part

Category Drug Registration

Article 10

- (1) Drug registrations are categorized into registration of new and registration of drug variations.
- (2) New drug registration as meant in sub-article (1) consist of :
 - a. Category 1 : is new drug registration with new active pharmaceutical ingredient or new derivative or new combination or biological product with new active ingredient or new combination or in a new dosage form;



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- b. Category 2 : is new drug registration with old composition in a new dosage form or new strength or similar biological product;
 - c. Category 3 : is registration of drug or biological product with old composition with :
 - 3.1. new indications
 - 3.2. new posology
 - d. Category 4 : is registration of copy drug :
 - 4.1. copy drug with a trade name
 - 4.2. copy drug with a generic name
 - e. Category 5 : is registration of other preparation containing drug
- (3) Registration of drug variation as meant in sub-article (1) consists of :
- a. Category 6 : is registration of copy drug which has already obtained a marketing authorization with a modification from what has already been approved in Indonesia :
 - 6.1. Modification or addition of dosage form with different posology or route of administration.
 - 6.2. Modification or addition of dosage form
 - 6.3. Modification or addition of drug strength
 - 6.4. Modification of drug composition
 - 6.5. Modification of copy drug with trade name into copy drug with generic name or inverse.
 - b. Category 7 : is registration of drug that has obtained a marketing authorization with a modification of label claim which influence drug safety.
 - c. Category 8 : is registration of drug which has obtained a marketing authorization with :
 - 8.1. Modification of inactive ingredient / excipient.
 - 8.2. Modification of the specifications and / or method of analysis.
 - 8.3. Modification of stability.
 - 8.4. Modification of the technology of production and / or manufacturing site.
 - d. Category 9 : is registration of drug that has obtained a marketing with a modification or addition to the packaging;



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- e. Category 10 : is registration of drug that has obtained a marketing authorization with :
- 10.1. Modification of the label claim which shall not influence the efficacy, safety and quality.
 - 10.2. Modification of packaging design.
 - 10.3. Change of factory name or the name of license-holder.
 - 10.4. Change of importer.
 - 10.5. Modification / addition of package size.
 - 10.6. Change of trade name without any change of formula and package form/type.

**CHAPTER V
POCEDURE FOR OBTAINING A MARKETING AUTHORIZATION**

**First Part
General
Article 11**

- (1) Drug registration shall be submitted by the applicant to the Head of the National Agency.
- (2) Drug registration consist of 2 (two) stages, that is pre-registration and submission of the registration dossier.
- (3) Submission of the registration dossier as stated in sub-article (2) is conducted by using registration forms and floppy disks, completed with supporting documents in line with valid provisions.
- (4) Registration data, related to evaluation and analysis of drug is confidentially protected by the Head of Agency.

**Second Part
Pre-Registration**

Pre-registration is a registration procedure that is conducted to decide the evaluation Path and the completeness of drug registration documents for category 1, category 2, category 3, category 4, category 5, category 6, and category 7 as meant in article 10.

Article 13

- (1) Pre-registration application must contain documents as stipulated in Attachment 2 and completed with the search result of drug trade name.



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- (2) Pre-registration documents as meant in sub-article (1) will be used to consider the evaluation Path accordance with Attachment 3 and must be completed with administrative documents as stipulated in Attachment 4.
- (3) Criteria for evaluation Path as stipulated in sub-article 92) must comply with Attachment 5 and if it is deemed necessary completed with the details of independent assessment report in line with Attachment 6.
- (4) Drug name meant in sub-article (1) might be a generic name or a trade name based on General Guideline of Drug Name in line with Attachment 7.

Article 14

The result of pre-registration will be communicated to the applicant in writing and it is binding.

Third Part

Registration Application

Article 15

- (1) Registration application is conducted by submitting registration dossier, than is by completing registration form and floppy disk and attaching the receipt of payment of evaluation and registration fee and the result of pre-registration.
- (2) Registration form or floppy disk as meant in article (1) shall be supplied by the directorate of Drug and Biological Product Evaluation.

Article 16

- (1) Upon Drug Registration, applicant is obliged to pay evaluation fee.
- (2) Evaluation fee as meant in article (1), is in conformity with the provisions of Government Regulation on the Tariff of a type of non tax state income (Penerimaan Negara Bukan Pajak = PNBP) valid to National Agency of Drug and Food Control.



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Article 17

- (1) For the purpose of evaluation on quality, applicant should submit drug sample for 3 (three) times of analysis and standard raw material conform to the specification and method of analysis of the active ingredient of the objective drug.
- (2) Copy drug is an exception of the provisions as meant in sub-article (1), submission of drug sample and standard raw material will be requested, if deemed necessary.
- (3) The executions of the submission of drug sample and standard raw material as meant in sub-article (1) and sub-article (2) will be stipulated separately by the Head of Agency.

Article 18

Registration of contracted drug, domestically products under license from overseas company, and imported drug, beside of complying the provisions of drug registration, should also comply to the provisions conform to Attachment 8.

Fourth Part

Registration Dossier

Article 19

- (1) Registration dossier as meant in article 15 sub-article (1) consists of registration forms with the administrative documents and supporting documents.
- (2) Administrative document as mean in sub-article (1) is the document that must be fulfilled for drug registration in line with Attachment 4.

Article 20

Supporting documents as meant in Article 19 sub-article (1) consist of :

- a. Quality and technology documents to ensure the quality of drug conforms to Attachment 9;
- b. Pre-clinical trial documents which should describe the profile of pharmacodynamic, pharmacokinetic as well as safety level for toxicity, before the human clinical trial, which conforms to the stipulation in Attachment 10 and pre-clinical trial report matrix conform to Attachment 11.
- c. Clinical trial document should be able to prove convincingly the efficacy and safety of finished drug in compliance to the stipulations in Attachment 12 and the clinical trial report matrix conform to Attachment 13.



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Article 21

- (1) Registration form as meant in Article 19 sub-article (1) should be completed with :
 - a. Package design artwork that includes label, box/outer package, strip/blister, catch cover, ampoule/vial, and other package conform to the provisions on the packaging and valid label acts, which represent a drug package design which will be marketed and should be completed with color design.
 - b. Brochure package insert/leaflet which represent a drug information.
- (2) Package design artwork as mean in sub-article (1) point a specification for generic drug, conform to the provisions on the standard specifications of generic drug.
- (3) Minimum information that should be printed on the package design as meant in sub-article (1) point a and sub-article (2) should conform to the stipulation in Attachment 14.
- (4) Minimum information that should be printed on the brochure/package insert/leaflet as meant in sub-article (1) point b should be conform to the stipulation in Attachment 15.

Article 22

- (1) For new registration as meant in the article 10 sub-article (2), the submitted dossier should consist of floppy disk that has been completed in line with the data in Form A and form of Forms A, Form B₁, Form B₂, Form B₃, Form B₄, Form C₁, Form C₂, Form C₃, Form D, and supporting documents for new registration for each category in line with Attachment 16.
- (2) Registration dossier of copy drug with an active ingredient that has already been available in the Electronic Information Standard (STINEL = Standar Informasi Elektronik), consist of floppy disk that has been completed in line with the data in Form A and Form B₂₁₋₁₃, and the forms of Forms A, Form B₁, Form B₂₁₄, Form B₄, Form C₁, and Form D.
- (3) Registration dossier of copy drug with an active ingredient that has no STINEL, consist of a floppy disk that has been completed with the data in line with Form A and the forms of Form A, Form B₁, Form B₂, Form B₃, Form C₁, and Form D.

Article 23

For registration drug variations as meant in Article 10 sub-article (3), the submitted dossier consist of a floppy disk which has been completed in line with data in Form A and the dossier forms and supporting documents for registration of drug variations as stipulated in Attachment 17.



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**Fifth Part
F o r m s
Article 24**

- (1) Form A contains informations about name and address of the applicant and manufacturing pharmaceutical industry and general information about drug to be registered.
 - a. Form B Contains documents that cover the aspects of efficacy, safety and the quality of registered drug and is binding, such as Form B1 (administrative documents), Form B2 (product information that cover the aspects of efficacy, safety and quality), Form B3 (the procedure of Batch numbering system) and Form B4 (price information);
 - b. Form C contains documents that must be attached to support the information mentioned in Form B2, that is Form C1 (documents on quality and technology), form C2 (pre-clinical trial documents) and Form C3 (clinical trial documents);
 - c. Form D contains a list of the submitted drug sample and its reference standard.
 - d. Registration forms as meant in sub-article (1) must conform to Attachment 18.

**Sixth Part
Forms Completion
Article 25**

- (1) Completion of registration forms and registration documents should follow the below provisions:
 - a. Completion of registration forms should be in Indonesian or in English;
 - b. Registration documents can be in Indonesian or in English;
 - c. Labeling of over the counter drug/limited over the counter drug must be in Indonesian;
 - d. Labeling of drugs for export only should at least be in English.
- (2) Guideline for the completion of registration forms conform to Attachment 19.
- (3) In completing registration forms as meant in sub-article (2), the description of active and inactive ingredients must conform to Attachment 20.



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**Seventh Part
Evaluation
Article 26**

- (1) Toward drug registration dossier which has fulfilled the provision as meant in Article 15 and Article 16, shall be evaluated in compliance with the provisions as meant in Article 3.
- (2) Evaluation as meant in sub-article (1) shall be grouped into new drug and biological product evaluation and copy drug evaluation.
- (3) The execution of evaluation for new drug registration is proceed through Path I (one), Path II (two) or Path III (three).

Article 27

- (1) Drugs that will be evaluated through path I (one) are:
 - a. Drugs that are indicated for the treatment/therapy of serious diseases and life-threatening diseases in human;
 - b. Generic essential drugs for public health program.
- (2) Drugs as meant in sub-article 91) are stipulated by the Head of Agency.

Article 28

Drugs that will be evaluated through Path II (two) are:

- a. New drug which has been approved in the group of countries that applied harmonization of evaluation system and 1 (one) county that has applied established evaluation system which is supported by an independent assessment report;
- b. New Drug which has been approved in 3 (three) countries that applied established evaluation system supported with independent assessment report.
- c. Copy drug without STINEL (Electronic Information Standard) and blood products.

Article 29

Drugs that are not included in Article 27 and Article 28 will be evaluated through Path III (three).



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Article 30

- (1) For the execution of evaluation, a national Committee on Drug Evaluation (KOMNAS POJ) has been founded.
- (2) Organization, Task and Functions of KOMNAS POJ as meant in sub-article (1) are stipulated separately by the Head of Agency.

Article 31

- (1) In case of further requirement of additional data for evaluation, the head of the National Agency will issue a written request by using a format conform with Attachment 21.
- (2) Applicant is obliged to submit additional data as meant in sub-article (1) within 120 (one hundred and twenty) days from the date of letter issuance.
- (3) In case of applicant was unable to fulfill the provisions as meant in sub-article (2) the Head of National Agency will issue a letter of rejection of the registration by using a format conform with Attachment 22.
- (4) In case of registration that is rejected as meant in sub-article (3), the applicant can resubmit a new registration with the documents as meant in Article 15 and completed with additional data as meant in sub-article (2).

Article 32

The result of efficacy and safety from KOMNAS POJ (National Committee of Drug Evaluation) will be informed in written form to the applicant with a format conform with Attachment 23.

Eighth Part

Decision Issuance

Article 33

- (1) Based on the recommendation of KOMNAS POJ, the Head of the National Agency will issue a decision form marketing authorization by using a format which conform with Attachment 24 or will reject by using a format conform with Attachment 25.
- (2) The timelines for decision issuance as meant in sub-article (1), will be issued after receiving complete registration dossier:
 - a. New registration Path I (one): 100 working days;



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- b. New registration Path II (two): 150 working days;
- c. New registration Path II (three) for new drug: 300 working days; copy drug with STINEL and drug for export only: 80 working days;
- d. Registration of drug variation category-6, category-7, category-8 and category-9: 80 working days;
- e. Registration of drug variation category-10 with latest information of labeling: 40 working days.

**Ninth Part
Hearing
Article 34**

- (1) In case of any objection upon/toward the result of efficacy and safety evaluation from KOMNAS POJ as meant in Article 32, applicant could submit a written application for hearing to the Head of Agency.
- (2) The application as meant in sub-article (1) should be submitted within 15 working days from date of issuance letter of the result of efficacy and safety evaluation.

**Tenth Part
Appeals
Article 35**

- (1) In case any objection upon rejection of a registration as meant in Article 33 sub-article (1), applicant could submit a written request for appeals to the Head of Agency.
- (2) Appeals as meant in sub-article (1) should be submitted within 6 months from the rejection date and the applicant can obtain two chances of appeals.
- (3) Appeals should be completed with new data and/or the data that has ever been submitted with accomplishment of justification.

**Eleventh Part
Resubmission of Drug Registration
Article 36**

In case of the rejection of registration for the reason of safety and efficacy, resubmission may be applied after 1 (one) year from the date of rejection.



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**Twelfth Part
Issuance of Marketing Authorization
Article 37**

- (1) Marketing authorization as meant in Article 33 sub article (1) is granted only to the applicant that fulfill the criteria of:
 - a. Administration;
 - b. Technical, presented as the result of evaluation on efficacy, safety, quality, usefulness and labeling.
- (2) Marketing authorization will be valid for 5 (five) years and should fulfill the valid provisions.
- (3) Renewal of drug marketing authorization is stipulated separately by the Head of Agency.

**CHAPTER VI
EXECUTION OF MARKETING AUTHORIZATION**

Article 38

- (1) Applicant which has obtained marketing authorization obliged to produce or import or distribute drug within 12 (twelve) months after the approval date issuance.
- (2) Execution of activities as meant in sub-article (1) should be reported and submit the marketed unit pack to the Head of Agency.
- (3) Submission of ready to distribute marketed unit pack as meant in sub article (2) shall be executed at least within 1 (one) month before the implementation of production, import or drug distribution.
- (4) Pay annual fee of marketing authorization in compliance with the valid provisions.
- (5) Annual fee as meant in sub article (4) is stipulated separately by the Head of Agency.

Article 39

- (1) Execution of drug import must be completed with Certificate of Analysis for each batch.
- (2) Execution of vaccine for domestic distribution and export should obtain a Certification of batch release by the Head of Agency.



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- (3) Execution of vaccines imported should obtain a Certification of Batch Release by the Head of Agency or Authorized Agency Staff from the original county where production take place.
- (4) Import of narcotic and psychotropic containing drug execution are stipulated separately by the Head of Agency.

**CHAPTER VII
RE-EVALUATION
Article 40**

- (1) The drug that has been granted marketing authorization can be re-evaluated/have periodic reviews by the Head of Agency.
- (2) Re-evaluation on a marketed drug will be done upon:
 - a. Post marketing surveillance revealed that the risk of the drug adverse effect out weight the drug efficacy.
 - b. Drugs with efficacy that is not better than placebo.
 - c. Drugs that failed the criteria of bioavailability/bioequivalence.
- (3) Upon drug which is re-evaluated as meant in sub-article (2) pharmaceutical industry/applicant is obliged to withdraw this drug from the market.
- (4) Re-evaluation is also applicable for the improvement of composition and drug formula.

**CHAPTER VIII
WITHDRAWAL OF MARKETING AUTHORIZATION
Article 41**

The Head of Agency may cancel marketing authorization by using a format conform with Attachment 26, in case of one of the below:

- a. Based on the investigation or monitoring of drug usage after market distribution, the drug failed to fulfill the criteria as meant in Article 3;
- b. Labeling and promotion deviated from marketing authorization;
- c. Not complying with the obligation as meant in Article 38;
- d. If during the successive 12 (twelve) months the drug has not been manufactured, imported or distributed.
- e. The license of applicant pharmaceutical industry or pharmaceutical wholesaler that register, manufacture, or distribute the drug has been cancelled.



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CHAPTER IX SANCTIONS

Article 42

The applicants who manufacture and/or distribute counterfeit drug will receive a sanction in line with the provisions of valid rules of law.

Article 43

- (1) Any individual who distribute finished drug that is not in compliance with the provisions in this decree, will be sanctioned with a punishment in line with provisions of valid rules of law.
- (2) Beside a sanction of punishment as meant in sub-article (1), an administrative sanction will be executed in the form of:
 - a. Written warning;
 - b. Temporary suspension of activities;
 - c. Withdrawal of marketing authorization;
 - d. Other administrative sanction in line with the valid rules of law.

CHAPTER X TRANSITIONAL PROVISIONS

Article 44

All provisions on the rules of law concerning the procedure of drug registration already issued before the stipulation of this decree, shall remain valid as long as they are not contradiction and/or being substituted with the provisions of this decree.

Article 45

This decree effective as of the date of stipulation and shall be amended and improved if in future a revision is needed.



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For public cognizance, this decree shall be published in the State gazette of the Republic of Indonesia.

Stipulated in : J A K A R T A

On : May 14. 2003

National Agency of Drug and Food Control
Head,



H. SAMPURNO