CONTROL SYSTEM OF TRADITIONAL MEDICINE

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OUTLINE

1. INTRODUCTION
2. CONTROL SYSTEM OF NADFC
3. REGULATION OF TRADITIONAL MEDICINE
INTRODUCTION
Traditional Medicine (TM) - Cultural Heritage

Increased Traditional medicines demand globally

NADFC STRATEGIC ROLE

- Improve the competitiveness of drug and food products in local and global markets
- Providing consumer protection

Forceful NADFC control system

Assure Safety, Quality and Efficacy Products
CONTROL SYSTEM OF NADFC
NADFC’S CONTROL SYSTEM

INDUSTRY

PRODUCTS

PRODUCTION FACILITY

PRODUCTS REGISTRATION

REGISTRATION NUMBER

GMP CERTIFICATE

DISTRIBUTION

PRODUCT SAMPLING AND LABORATORY TESTING

PRODUCTS

POST-MARKET CONTROL

INSPECTION OF PRODUCTION AND DISTRIBUTION FACILITY

SANCTIONS AND LAW ENFORCEMENT

CONSUMER

SAFETY AND EFFICACY ASSURANCE

PROMOTION AND LABELLING, PHARMACOVIGILANCE

Socialization
Traditional Medicine

Ingredients/mixture of ingredients

- Plant materials
- Animal materials
- Mineral materials
- Extracts
- Mixtures of materials

Used for treatment between generations

Applied in community
TM Safety, Quality and Efficacy Assurance

Registration number:
Registration approvals for medicinal products, traditional medicines, cosmetics, health supplements, and foods issued by NADFC so that these products can be legally distributed in Indonesia.

Exception for:

a. Research;
b. Limited imports;
c. Exhibition;
d. Jamu gendong (carried jamu);
e. Simplicia and galenical preparation.
1. Head of NADFC’s Regulation No. 29 year 2017 concerning Food and Drug Ingredients Importation Control to Indonesia
2. Head of NADFC’s Regulation No. 30 year 2017 concerning Food and Drug Importation Control to Indonesia

1. Ministry of Health Regulation Menteri Kesehatan No. 007 year 2012 concerning Traditional Medicine Registration
2. Head of NADFC’s Regulation No. HK.00.05.41.1384 year 2005 concerning Criteria and Registration Procedure of Traditional Medicine, Standardized Herbal Medicine and Phytopharmaca
3. Head of NADFC’s Regulation No. 21 year 2015 concerning Procedure of Clinical Test Approval
Head of NADFC’s Regulation No. HK.03.1.23.06.11.5629 year 2011 concerning Technical Requirement of Traditional Medicine GMP

Head of NADFC’s Regulation No. 12 year 2014 concerning Quality Requirement of Traditional Medicine
HEAD OF NADFC’S REGULATION NO. HK.00.05.41.1384 YEAR 2005 CONCERNING CRITERIA AND REGISTRATION PROCEDURE OF TRADITIONAL MEDICINE, STANDARDIZED HERBAL MEDICINE AND PHYTOPHARMACAE
CLASSIFICATION OF TRADITIONAL MEDICINE (TM)

LOCAL TM
- LICENSED TM
- NON LICENSED TM
- STANDARDIZED HERBAL MEDICINE
- PHYTO PHARMACA
- CONTRACT (TOLL OUT MANUFACTURING)

IMPORT TM

Registrant
- IOT, IF
- IOT, IF, UKOT
- IOT, IF, Direct Appointed Local’s Company

Registrant

- IOT: Industri Obat Tradisional (Traditional Medicine Industry)
- IF: Industri Farmasi (Pharmaceutical Industry)
- UKOT: Usaha Kecil Obat Tradisional (Small Traditional Medicine Enterprise)
CRITERIA of TM

- Active ingredient and excipients fulfill quality, safety and efficacy requirements
- Fulfill GMP’s requirement
- Label information shall be written clearly comprehensible and objective
Registration Procedure of TM

Note:
Clinical trial to be conducted in Indonesia shall follow Indonesia regulation (Perka 21/2015)
**SAFETY**
- 1. No prohibited raw materials
- 2. No chemical substances raw materials
- 3. Toxicity data or others scientific data

**Efficacy**
- 1. Amount of active ingredients
- 2. Evaluation based: empirical data/scientific data to support claim

**Quality**
- 1. Formulation
- 2. Production process
- 3. CoA of raw material
- 4. CoA of product
- 5. Stability data
- 6. Quality requirement
- 7. Microbial Contamination
- 8. Heavy metal contamination, etc

**Labeling**
- Indication
- Direction of use
- Pack sizes
- Compotition
- Expiration date
- Storage condition
- Registration number
- Name and address of manufacturer
- Warning, Caution (if any) etc

**Requirement of Traditional Medicine Administration**
- Industry lisence
- GMP
- LoA
- CFS
- etc
HEAD OF NADFC’S REGULATION NO. 30 YEAR 2017 CONCERNING FOOD AND DRUG IMPORTATION CONTROL TO INDONESIA
IMPORTATION REQUIREMENTS FOR TRADITIONAL MEDICINE

1. Shall have registration number

2. Shall comply with all regulations regarding importation

3. Shall be completed with SKI

*Ministry of Trade’s Regulation

*Head of NADFC’s Regulation No. 30 year 2017 concerning Food and Drug Importation Control to Indonesia

*Head of NADFC’s Regulation No. 29 year 2017 concerning Food and Drug Ingredients Importation Control to Indonesia
HEAD OF NADFC’S REGULATION NO. 12 YEAR 2014 CONCERNING QUALITY REQUIREMENTS OF TRADITIONAL MEDICINE
QUALITY REQUIREMENTS OF TM

TM QUALITY REQUIREMENTS

RAW MATERIALS

FINISHED PRODUCTS

• MATERIA MEDIKA INDONESIA
• INDONESIAN HERBAL PHARMACOPEA
• OTHERS PHARMACOPEA/SCIENTIFIC REFERENCE
PARAMETERS OF TM QUALITY REQUIREMENTS

FOR INTERNAL USE
(Powder, Capsule, Tablet, etc)

FOR EXTERNAL USE
(Liquid, semi solid and solid)
PARAMETERS OF TM QUALITY REQUIREMENTS

INTERNAL USE
- PHYSICAL APPEARANCE
- WATER CONTENT
- WEIGHT UNIFORMITY
- DISINTEGRATION
- MICROBIAL CONTAMINATION
- TOTAL AFLATOXIN
- HEAVY METAL CONTAMINATION
- Etc (SWEETENER)

EXTERNAL USE
- PHYSICAL APPEARANCE
- WATER CONTENT (Solid dosage form)
- DISINTEGRATION (Solid dosage form)
- WEIGHT UNIFORMITY (Solid dosage form)
- MICROBIAL CONTAMINATION
- Etc (PRESERVATIVES, COLORANTS)
THANK YOU