

## **CONTROL SYSTEM OF TRADITIONAL MEDICINE**

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# **OUTLINE**



1

### **INTRODUCTION**

2

**CONTROL SYSTEM OF NADFC** 



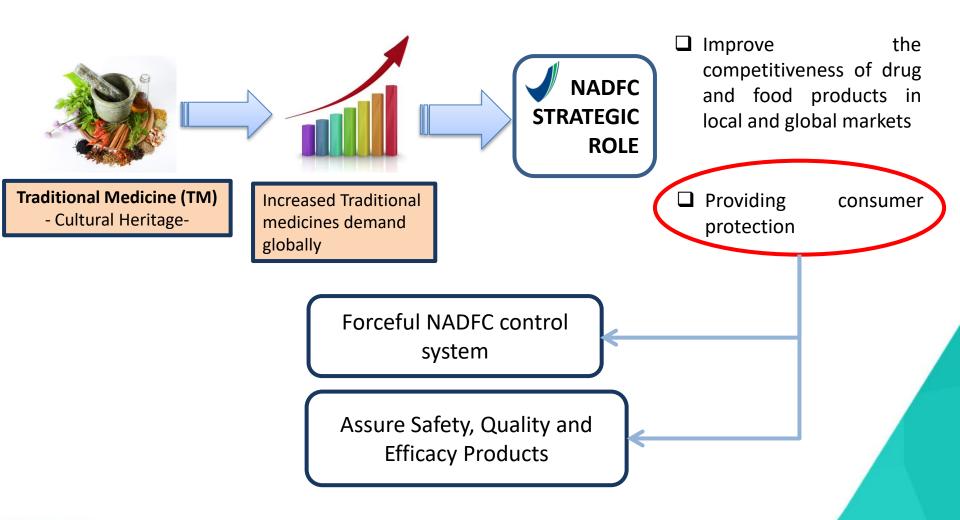
**REGULATION OF TRADITIONAL MEDICINE** 





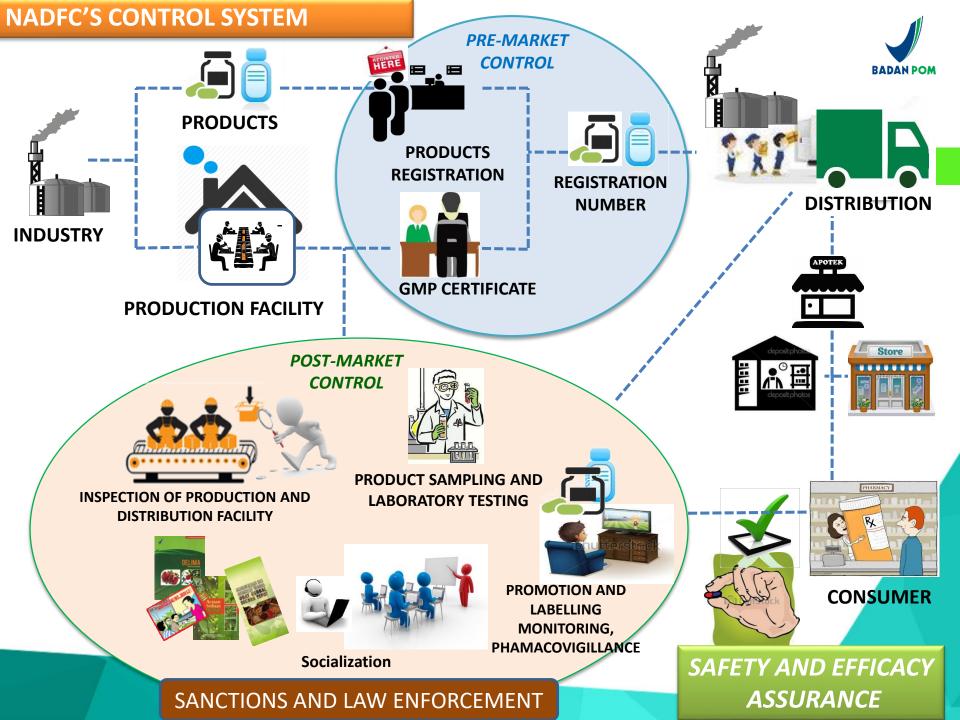
# **BACKGROUND**



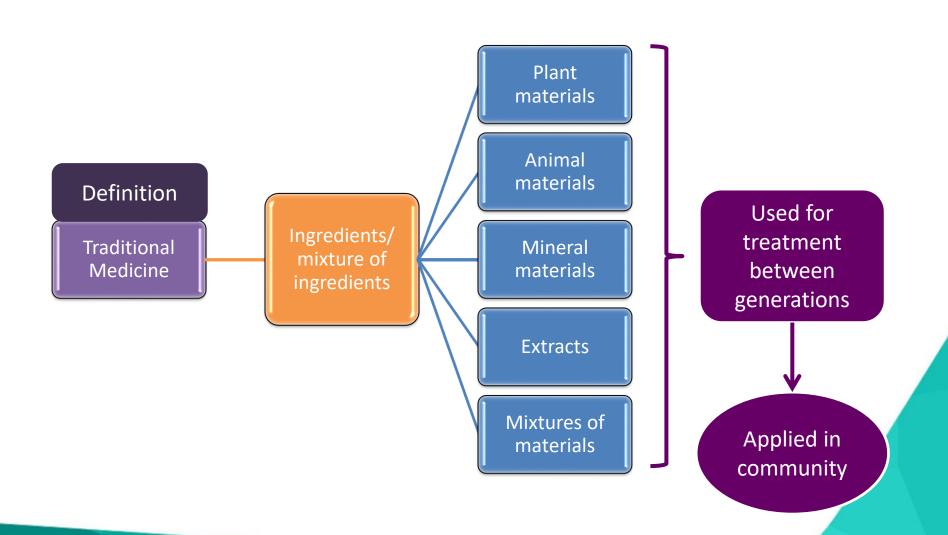












## NADFC'S CONTROL SYSTEM





TM Safety,
Quality and
Efficacy
Assurance



TM distributed in Indonesia must have Registration Number from NADFC



### **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.







### **REGULATION OF TRADITIONAL MEDICINE**





- 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



- 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

## **REGULATION OF TRADITIONAL MEDICINE**



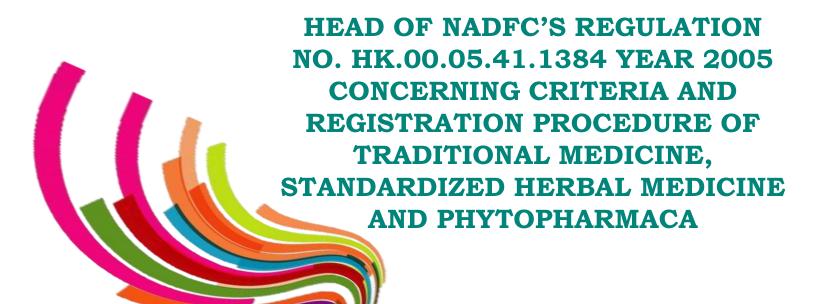
Production |

Head of NADFC's
Regulation No.
HK.03.1.23.06.11.5629
year 2011 concerning
Technical
Requirement of
Traditional Medicine
GMP



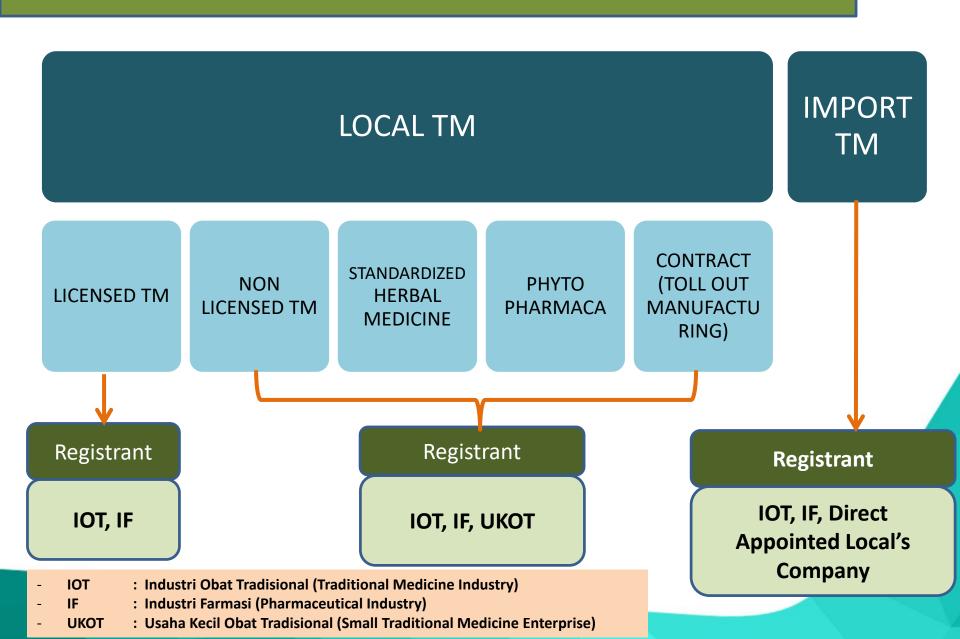
Head of NADFC's
Regulation No. 12 year
2014 concerning Quality
Requirement of
Traditional Medicine





# **CLASSIFICATION OF TRADITIONAL MEDICINE (TM)**





# **CRITERIA of TM**

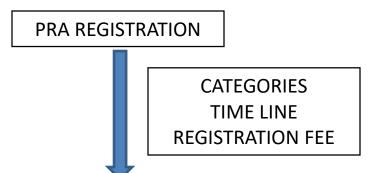


Active ingredient and excipients fulfill quality, safety and efficacy requirements

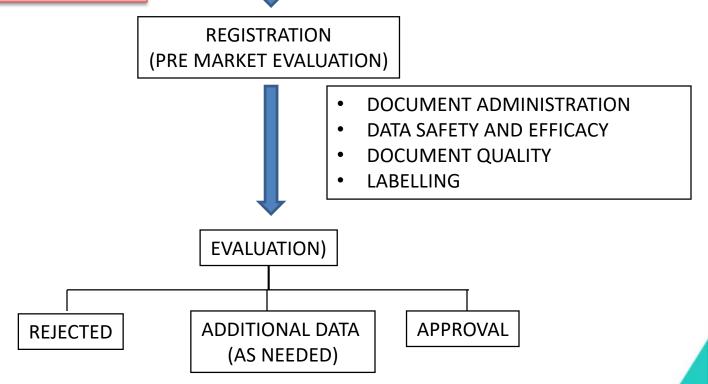
Fulfill GMP's requirement

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)

# REQUIREMENT OF TRADITIONAL MEDICINE

**SAFETY** 

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

1. No prohibited raw materials

**EFFICACY** 

- 2. No chemical substances raw materials
- 3. Toxicity data or others scientific data

**ADMINISTRATION LABELLING** (Industry lisence, GMP, LoA, CFS, etc)

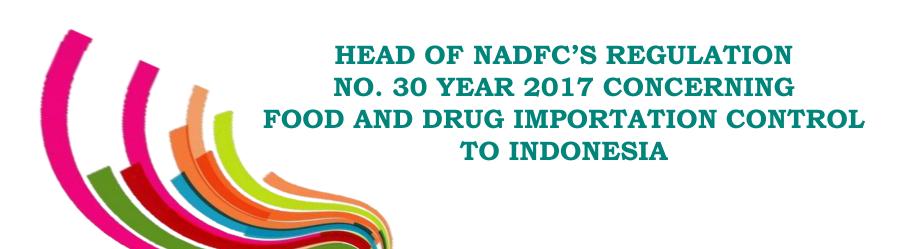
**QUALITY** 

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

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





# 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





# 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)
- WEIGT UNIFORMITY (Solid dosage form)
- MICROBIAL CONTAMINATION
- Etc (PRESERVATIVES, COLORANTS)

