



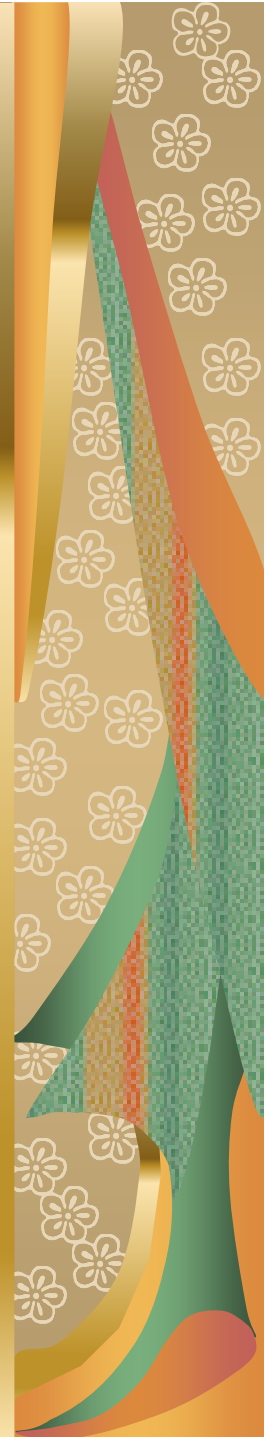
TRADITIONAL MEDICINES IN INDONESIA



THE NATIONAL AGENCY
OF DRUG AND FOOD CONTROL

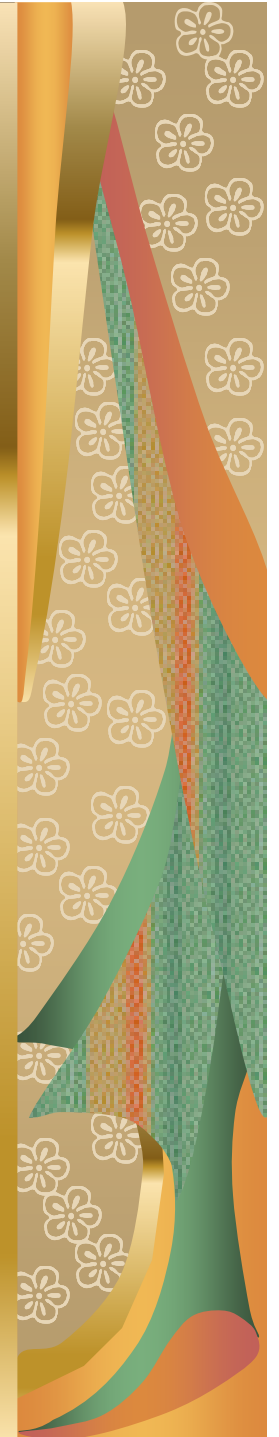
Traditional Medicines

- Traditional Medicines (TM) have been used by Indonesian society since ancient times and empirically passed on from generation to generation.
- TM have been used to maintain, and promote the human health, prevention as well as to reduce symptomatic disorders and has made great contribution to health.
- The use of TM is still prominent and take an important role as an alternative to Conventional medicines.



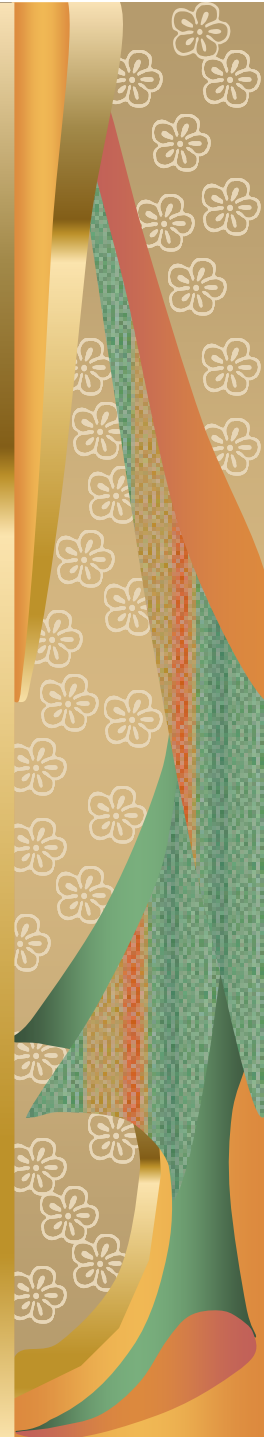
TM cont'd

- The regulation of TM follow WHO Framework on key component of Drug Regulation with some adjustment to suit the country's needs while on the other hand can still provide a control mechanism to protect the community from the risk of non compliance TM products.
- Within this regulatory framework, the essential regulatory elements among other are :



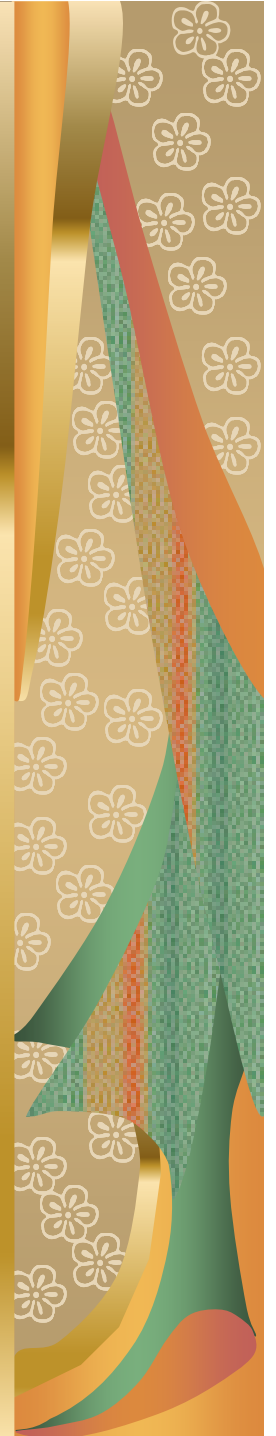
TM cont'd

- ❏ Standardization of raw material and finished product
- ❏ GMP implementation
- ❏ Pre-marketing evaluation of quality, safety and efficacy of finished product as well as advertisement
- ❏ Post marketing control:
 - ❏ Sampling
 - ❏ Laboratory testing
 - ❏ Inspection of GMP implementation
 - ❏ Monitoring of adverse reaction, labeling, advertisement
 - ❏ Public warning
 - ❏ Product recall
 - ❏ Law enforcement



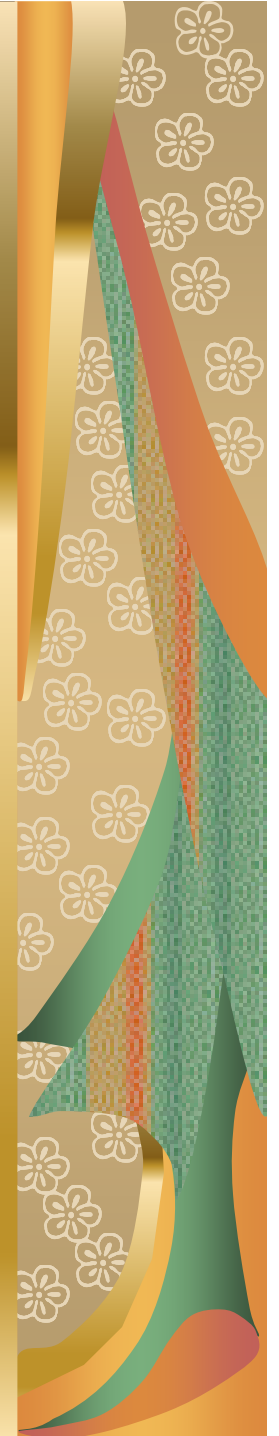
TECHNICAL REQUIREMENT FOR REGISTRATION

- The TM must be registered to NADFC before marketed to evaluate quality, safety and efficacy except product produced by home industry, jamu pedler
- The technical requirement for registration as follows:
 - Limit of contaminant, heavy metal etc
 - Water content,
 - Stability data
 - Safety data/ Toxicity data if needed(If safety profile have not been established)
 - Claim or efficacy data
 - Product containing bovine derived must be BSE free



Labeling requirement :

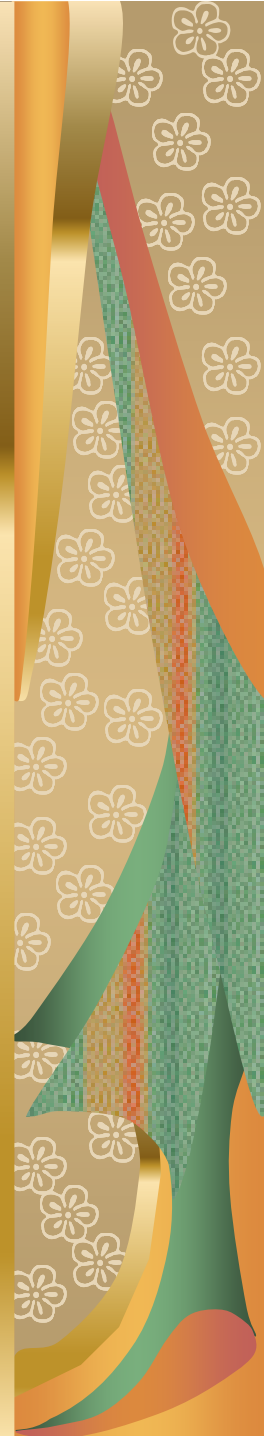
- Product Name
 - Composition
 - Indication or claim
 - Direction of use and dosage
 - Warning, Contra Indication and Side Effect (if any)
 - Name and address of manufacturer or importer
 - Labeling should be mentioned in Indonesian Language beside other language(English etc
 - Specific labeling for product containing substances from porcine origin
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- Registration licensed is valid for 5 years.
 - Applicant have to pay Registration Fee



TIME LINE FOR REGISTRATION

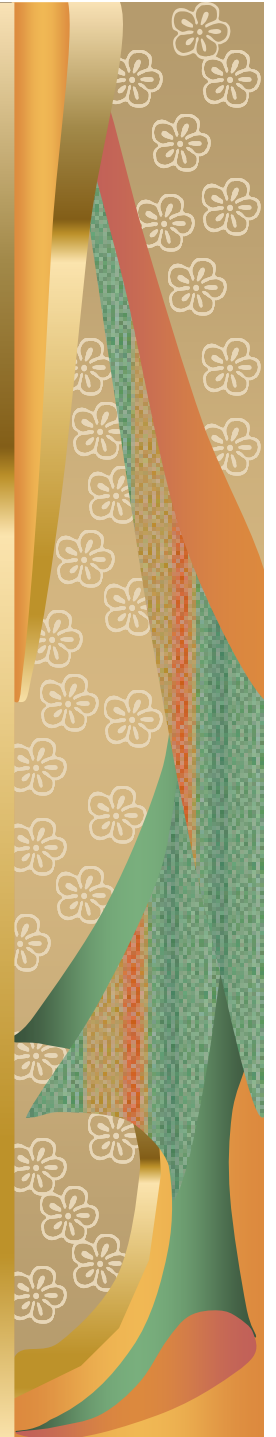
Based on risk of the product,time line for reg. is categories into 3 lines as follows:

1. 7-15 wd for low risk
2. 30-60 wd for medium risk
3. 90-120 wd for high risk



PROHIBITED

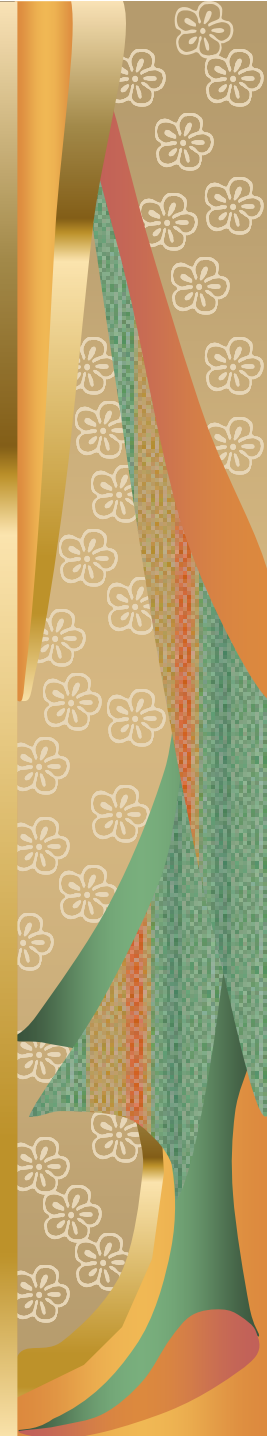
1. Adulteration(containing isolated chemical substances)
2. Narcotics & Psychotropics
3. Suppositories except for haemorrhoid
4. Sterile preparation(injection, eye prep.)
5. Vaccine
6. Human part derived
7. Intra vaginal prep
8. Negative list substances
9. Endanger species



Classification of Indonesian herbal medicines

TM is classified into three types namely :

- ❑ Jamu
- ❑ Standardized Herbal Medicines
- ❑ Phytopharmaca



CLASSIFICATION OF INDONESIAN TRADITIONAL MEDICINES (3 SCHEMES)



Jamu
(Indonesian
indigenous
Traditional
Medicines)



**Standardized
of Herbal
Medicines**



Phytopharmaca
(Scientific based
evidence)

CRITERIAS FOR THE JAMU, STANDARDIZED HERBAL MEDICINE, AND PHYTOPHARMACA

- ❖ **Jamu is Indonesian Traditional Medicines that safety and efficacy based on empirical experiences and traditionally used.**



- ❖ **Standardized herbal medicines are Indonesian Traditional Medicines which the safety and efficacy have been proven by pre clinical study. (Toxicity and Pharmacodynamic studies)**
- ❖ **Phytopharmaca is Indonesian Traditional Medicines which the safety and efficacy have been proven by pre clinical and clinically studies**

TERIMA KASIH

THANK YOU

BADAN PENGAWAS OBAT DAN MAKANAN