

# WITHDRAWAL AND DESTRUCTION OF TRADITIONAL DRUGS THAT DO NOT MEET QUALIFICATIONS

(Regulation of the Chief of the Food and Drug Supervisory  
Board No. 5/2016 dated March 28, 2016)

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## Article 5

- (1) The withdrawal as referred to in Article 3 paragraph (2) is done to :
  - a. all batches circulated for traditional drugs containing drug chemical materials;
  - b. relevant batches for traditional drugs containing pathogenic bacteria and/or failing to meet quality conditions; and/or
  - c. all batches of traditional drugs that do not meet provisions on designation as referred to in approval of a circulation permit.
- (2) A follow up to the finding of traditional drugs containing pathogenic bacteria, besides being withdrawn as referred to in paragraph (1), the holder of circulation permit shall also make a correction and prevention of the cause of products containing pathogenic bacteria.

## Article 6

- (1) The holder of circulation permit shall also withdraw traditional drugs if traditional drugs fail to meet conditions according to the conditions according to the result of test based on internal audit.

- (2) The withdrawal of traditional drugs as referred to in paragraph (1) shall be reported to the Chief of the Board according to provisions.

## Article 7

If traditional drugs do not meet the qualifications as referred to in Article 2, officer shall take safeguard as a follow up action according to provisions.

## CHAPTER IV DESTRUCTION

### Article 8

- (1) Traditional drugs that have been withdrawn from circulation by the holder of a business permit shall be destroyed.
- (2) In connection with destruction as referred to in paragraph (1), the holder of a circulation permit shall make
  - a. Official report of destruction; and
  - b. Report of destruction to the Chief of the Board.
- (3) Example of official report of destruction as referred to in paragraph (2) letter a is contained in the attachment which is an integral part of this

Regulation of the Chief of the Board.

- (4) The destruction done by the holder of circulation permit as referred to in paragraph (1) shall meet conditions:
- not polluting the environment;
  - not endangering the health of nearby residents; and
  - being witnessed by officer.
- (5) If the holder of circulation permit does not likely withdraw traditional drugs due to the difficult location, the owner of distribution facility at the request of the holder of circulation permit can destroy them himself/herself and witnessed by officer.

#### Article 9

- The owner of facility or proxy shall destroy traditional drugs without circulation permit and/or having passed the expiry limit.
- The destruction as referred to in paragraph (1) shall be done according to provisions as referred to in Article 8 paragraphs (2), (3), and (4).

#### Article 10

- Excepted from provisions as referred to in Article 8 for traditional drugs that do not meet provisions on designation and release of designation without destroying content can have their designation destroyed.
- If the release of designation leads to destroying the content the destruction shall be done along with traditional drugs.
- The traditional drugs as referred to in paragraph (1) can be designated again by observing the good practice of making traditional drugs (CPOTB).

### CHAPTER V

### SANCTIONS

#### Article 11

Violation of provisions in this Regulation of the Chief of the Board may be subject to administrative sanctions :

- stern warning;
- moratorium on production activity;
- moratorium on the import of goods that do not meet qualifications;
- moratorium on registration of products within 6 (six) months; and/or

- e. cancellation of circulation permit.

CHAPTER VI

CONCLUSION

Article 12

When this Regulation of the Chief of the Board begins to take effect, Regulation of the Chief of the Food and Drug Supervisory Board No. HK.03.1.23.02.12.1248 of 2012 concerning the Criteria and Procedure of Withdrawing Traditional Drugs that do not meet qualifications shall be declared null and void.

Article 13

This Regulation of the Chief of the Board shall begin to take effect as from the date of promulgation.

For public cognizance, this Regulation of the Chief of the Board shall be promulgated by placing it in the State Gazette of the Republic of Indonesia.

Stipulated in Jakarta

On March 28, 2016

THE CHIEF OF THE FOOD AND DRUG SUPERVISORY BOARD OF  
THE REPUBLIC OF INDONESIA,

sgd.

ROY A. SPARRINGA

Promulgated in Jakarta

On April 4, 2016

THE DIRECTOR GENERAL OF LAWS AND REGULATIONS AT THE LAW AND HUMAN RIGHTS  
MINISTRY OF

THE REPUBLIC OF INDONESIA,

sgd.

WIDODO EKATJAHJANA

STATE GAZETTE OF THE REPUBLIC OF INDONESIA  
OF 2016 NO. 498

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