

PROHIBITION FROM PRODUCING AND CIRCULATING TRADITIONAL DRUG AND FOOD SUPPLEMENT CONTAINING PAUSINYSTALIA YOHIMBE PLANTS (Regulation Head of Food and Drugs Supervisory Body of R.I Number HK.03.1.23.05.12.3428 Year 2012, dated May 31, 2012)

WITH THE BLESSING OF THE ONE AND ONLY GOD
THE HEAD OF FOOD AND
DRUGS SUPERVISORY BODY
OF THE REPUBLIC OF INDONESIA,

Considering:

- a. that the society must be protected from traditional drug and food supplement being in circulation that fail to comply with the requirements for security, remedy/benefit and quality;
- b. that security on the use of traditional drug and food supplement that are incessantly circulated must be monitored;
- c. that there are reports from various countries stating the side effect to the stimulation and paralysis in the nerve system resulting from using traditional drug and food supplement that contain Pausynistalia Yohimbe plants;
- d. that to improve consumer protection in Indonesia from possible risk from side effect referred to in

letter c, it is necessary to issue prohibition from using Pausynistalia Yohimbe plants in traditional drug and food supplement;

- e. that based on the consideration referred to in letters a, b, c, and d, it is necessary to stipulate Regulation of the Head of Food and Drugs Supervisory Body concerning Prohibition from Producing Traditional Drug and Food Supplement containing Pausynistalia Yohimbe plants;

In view of:

1. Law Number 8 Year 1999 (BN No. 6311 pgs. 5B-11B) concerning Consumer Protection (Statute Book of the Republic of Indonesia Year 1999 Number 42, Supplement to Statute Book of the Republic of Indonesia Number 3821);
2. Law Number 36 Year 2009 concerning Health (Statute Book of the Republic of Indonesia Year 2009 Number 144, Supplement to Statute Book of the Republic of Indonesia Year 2009 Number 5063);

3. Government Regulation Number 72 Year 1998 concerning Safeguarding Pharmaceutical Preparation and Health Apparatus (Statute Book of the Republic of Indonesia Year 1998 Number 138, Supplement to Statute Book of the Republic of Indonesia Number 3781);
4. Presidential Decree Number 103 Year 2001 concerning Capacity, Duty, Function, Authority, Organizational Structure, and Work Procedure of Non-Departmental Government Institution as amended several times and lately amended by Presidential Regulation Number 64 Year 2005;
5. Presidential Decree Number 110 Year 2001 concerning Organizational Unit and Duty of Echelon I of Non-Departmental Government Institution as amended several times and lately amended by Presidential Regulation Number 52 Year 2005;
6. Regulation of the Minister of Health Number 006 Year 2012 concerning Traditional Drug Industry and Business;
7. Regulation of the Minister of Health Number 007 Year 2012 concerning Registration of Traditional Drug;
8. Decision of the Head of Food and Drugs Supervisory Body Number 02001/SK/KBPOM Year 2001 concerning Organization and Work Procedure of Food and Drugs Supervisory Body as amended by Decision Head of Food and Drugs Supervisory Body Number HK.00.05.21.4231 Year 2004;
9. Decision Head of Food and Drugs Supervisory Body Number HK.00.05.23.3644 Year 2004 concerning Principal Provision on Food Supplement Supervision;
10. Regulation Head of Food and Drugs Supervisory Body Number HK.00.05.41.1381 Year 2005 concerning Procedure for Registering Food Supplement;
11. Regulation Head of Food and Drugs Supervisory Body Number HK.00.05.41.1384 Year 2005 concerning Criteria and System for Registration Standard Traditional Medicine, Herbal Medicine, and Fitofarmaka (?);

DECIDES:

To stipulate:

REGULATION OF THE HEAD OF FOOD AND DRUGS SUPERVISORY BODY CONCERNING PROHIBITION FROM PRODUCING AND CIRCULATING TRADITIONAL MEDICINE AND FOOD SUPPLEMENT THAT CONTAINS PAUSINYSTALIA YOHIMBE PLANTS.

First:

Prohibit from producing and circulating traditional drug and food supplement that contain Pausynistalia Yohimbe plants.

Second:

Revoke the registration approval for traditional drug and food supplement that contain Pausynistalia Yohimbe plants.

Third:

Withdraw from circulation all traditional drug and food supplement referred to in the Second dictum within three (3) months effective as of the date this Regulation is enacted.

Fourth:

Any violation to the provisions in this Regulation is subject to penalty according to the provisions in the statutory regulation.

Fifth:

This Regulation takes effect on the date it is enacted.

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

Stipulated in Jakarta

Dated May 31, 2012

HEAD OF FOOD AND DRUGS SUPERVISORY BODY
OF THE REPUBLIC OF INDONESIA,

sgd.

LUCKY OEMAR SAID

Enacted in Jakarta

Dated June 13, 2012

MINISTER OF LAW AND HUMAN RIGHTS
OF THE REPUBLIC OF INDONESIA,

sgd.

AMIR SYAMSUDIN

STATE GAZETTE OF THE REPUBLIC OF INDONESIA
YEAR 2012 NUMBER 623

(MA)