REGULATION OF
THE HEAD OF NATIONAL AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA
NUMBER HK.03.1.3.12.11.10692 OF 2011
ON
IMPORTATION CONTROL OF PHARMACEUTICAL PRODUCTS

HEAD OF NATIONAL AGENCY OF DRUG AND FOOD CONTROL
REPUBLIC OF INDONESIA,

Considering :

a. registered/marketed drug, including imported drug must meet the requirements of safety, efficacy and quality;
b. the regulation of Head of National Agency of Drug and Food Control number HK.00.05.1.3459, 2005, on Importation Control of Drug, is no longer appropriate with the development of science and technology, therefore it needs to be revised;
c. based on all the afore mentioned in point a and b, it is necessary to stipulate the Regulation of Head of National Agency of Drug and Food Control on Importation Control of Drug;

In View of :

1. Consumer Protection Act Number 8, 1999 (State Gazette Year 1999 Number 42, Supplementary State Gazette Number 3821);
2. Health Act Number 36, 2009 (State Gazette Year 2009 Number 144, Additional State Gazette Number 5063);
3. Presidential Decree Number 103, 2001 regarding Position, Mandate, Function, Authority, Organizational Structure and Working Procedures of Non Department Government Institution as already amended by Presidential Decree Number 64, 2005;
4. Presidential Decree Number 110, 2001 regarding Organization Units and Tasks of Echelon I Non Department Government Institution as already amended by Presidential Decree No. 52, 2005;
5. Regulation of the Minister of Health of the Republic of Indonesia Number 1799/Menkes/Per/XII/2010 regarding the Pharmaceutical Industry;

6. Decree of the Head of National Agency of Drug and Food Control Number 02001/SK/KBPOM, 2001 regarding the Organization and Administration of Drug and Food Control Agency, as amended by Decree of the Head of the NADFC Number HK.00.05.21.4231 of 2004;
7. Decree of the Head of National Agency of Drug and Food Control Number HK.00.05.3.2522, 2003 regarding the Implementation of Guideline of Good Distribution Practices;
8. Decree of the Head of National Agency of Drug and Food Control Number HK.00.05.23.4415 of 2008 regarding the Implementation of Electronic Systems of the National Single Window Framework in the National Agency of Drug and Food Control ;
9. Decree of the Head of National Agency of Drug and Food Control Number HK.00.05.23.4416 of 2008 regarding Determination of Service Level Arrangement in the National Agency of Drug and Food Control on National Single Window Framework;
10. Decree of the Head of National Agency of Drug and Food Control Number HK.00.06.331.3.1655 of …… regarding Batch/ Lot Release Procedures of Vaccines for Human;

DECIDES:

To stipulate : REGULATION OF THE HEAD OF NATIONAL AGENCY OF DRUG AND FOOD CONTROL REPUBLIC OF INDONESIA ON IMPORTATION CONTROL OF PHARMACEUTICAL PRODUCTS.

CHAPTER I
GENERAL PROVISIONS
Article 1

In this Decree

1. Marketing authorization is a registration approval of drug to be marketed in the territory of Indonesia.
2. Imported drug is drug that manufactured or produced by foreign pharmaceutical industry, it can be as a finished products or bulk in a primary packaging and will be entered/shipped and marketed in Indonesia.
3. Imported drugs as referred to in point number 2 above, exclude narcotics, psychotropics and precursors.
4. Pharmaceutical industry is an entity that has a license from the Minister of Health to manufacture drug or drug substance.
5. Pharmaceutical Distributor/Wholesalers is an entity (of supply chain) which has license to perform procurement, storage, distribution of drugs and / or drug substances in a massive number, and in accordance with related legislations and provisions.
6. Drug Importation is process of importation of drug and its entry or shipment into the territory of Indonesia.
7. Batch/ lot release is evaluation process by the NADFC for each batch / lot of imported vaccine and sera for human, prior to approval release for use.
8. Batch/lot release certificate is an official document that allows a manufacturer to issue a certain batch / lot as confirmation that the batch / lot meet the applicable specifications and requirements.e specifications and requirements.
9. Pre-qualification by the World Health Organization (WHO) is a WHO assessment procedures to prove that the vaccines meet the specifications of the acceptance assessment procedures of United Nations (UN) and the requirements as recommended by the WHO, including Good Manufacturing Practices for the vaccines. The assessment includes an evaluation to the vaccine production facilities and the functions of the NADFC by WHO.
10. Summary protocol of batch / is a document containing a summary of the manufacturing process and test results of a batch / lot of vaccine, which is certified and signed by the responsible person in the vaccines manufacturer.
11. Head is Head of NADFC , who has responsibility for Drug and Food Control in Indonesia.

CHAPTER II

IMPORTATION OF PHARMACEUTICAL PRODUCTS

Article 2

(1) Drug Importation can only be done by the Pharmaceutical Industry which hold marketing authorization from the Head of the NADFC.

(2) Pharmaceutical Industry as referred to in paragraph (1) may appoint a Pharmaceutical Distributor/Wholesaler to import their drug.

Article 3

(1) Importation as referred to in Article 2 must be conducted in accordance with legislations and provisions on importation.

(2) In addition to the legislation and provisions as referred to in paragraph (1), it also must get approval of importation of drug borne by Head of NADFC.

(3) Approval as referred to in paragraph (2) is an importation approval letter or certificate.

CHAPTER III

APPLICATION PROCEDURES

Article 4

(1) Letter or Certificate as referred to in Article 3 paragraph (3) are provided upon request.

(2) Procedures for the application as referred to in paragraph (1) is an electronic submission through the NADFC website (www.pom.go.id) or through the NSW BPOM (e-bpom.pom.go.id).

(3) The approval process time line is no later than 1 (one) business day.

Article 5

The application as referred to in Article 4, shall be atttached with the following documents:

a. marketing authorization of imported pharmaceutical products/ bulk products;
b. Certificate of Analysis (CoA) issued by manufacturer for each batch / lot.
c. letter of appointment, if the import done by the executor appointed by the marketing authorization holder;
d. invoices;
e. proof of payment of State Revenue (non-tax revenues); and
f. Bill of Lading (B / L) or Air Way Bill (AWB).

Article 6

Importation of vaccines for human use, should also be completed with the following documents:

a. batch/lot release certificate issued by the authority agency of a releasing country for every single importation; and
b. summary batch / lot protocol issued by the manufacturer.

Article 7

specifically in CoA of sera for human use should be declared the source of active ingredients);

Article 8

SKI is given at the latest 1 (one) working day after all requirements complete and correct.

Article 9

(1) Each Certificate of Importation is only valid for 1 (one) entry or shipment.

CHAPTER IV

IMPLEMENTATION OF IMPORTATION

Part One

General

Article 10

(1) All documents relate to importation of drug substances must be documented in accordance with the Technical Guidelines of Good Distribution Practices, and therefore it allows an inspection done easily.

(2) The documents as referred to in paragraph (1) should be available any time and subject to inspection by inspector of NADFC.

Part Two

Special

Article 11

(1) Importation of vaccines and sera which has obtained its Letter or certificate of importation by NADFC, can only be distributed/marketed after sampling, evaluation, and testing are done and the results must meet the requirements for vaccines and sera.

(2) Sampling, evaluation, and testing as referred to in paragraph (1) conducted/carried out by the NADFC

(3) ...

Article 12

(1) Importation of vaccines and sera which have obtained WHO pre-qualification certificate, NADFC will carry out:

a. evaluation of summary protocol of batch / lot, the certificate of analysis, labeling and potency test data, and

b. appearance testing.

(2) The evaluation and testing results as referred to in paragraph (1) will be presented as a certificate of batch/lot release.

3) Certificate of batch/lot release as referred to in paragraph (2) will be issued within and or no later than 10 (ten) working days after sampling was conducted.

Article 13

(1) Importation of vaccines and sera which have not obtained WHO pre-qualification, NADFC will carry out:

a. evaluation of summary protocol of batch / lot of, the certificate of analysis, labeling and potency test data;

b. appearance testing

c. Potency testing and / or other appropriate testing as necessary.

(2) The evaluation and testing results as referred to in paragraph (1) will be presented as a

certificate of batch/lot release and certificate of analysis.

(3) certificate of batch/lot release and certificate of analysis as referred to in paragraph (2) will be issued within and or no later than 65 (sixty five) working days after sampling was conducted.

CHAPTER V

COST

Article 14

Upon request as referred to in Article 4 paragraph (1) and the sampling, evaluation and testing as referred to in Article 10 and Article 11 subject to the State Revenue in accordance with statutory regulations.

CHAPTER VI

ADMINISTRATIVE ACTION

Article 15

(1) Pharmaceutical Industry or Pharmaceutical Distributor/Wholesalers who imports drug substances and fail to comply with the legislation/provisions as referred to in Article 3 and / or Article 7 may be subjected to administrative sanctions.

(2) The administrative sanctions as referred to in paragraph (1) can be as follows:
a. written warning letter;
b. temporary suspension of activities; or
Other administrative sanctions in accordance with the legislation/provisions

CHAPTER VII

TRANSITIONAL PROVISIONS

Article 16

At the time this Regulation applies, the petition was filed SKI and has not received approval, it is processed based on the Regulation of the Head of Food and Drug Supervisory Agency HK.00.05.1.3459 No. 2005 on the Import Control Drug Importation.

CHAPTER VIII

FINAL PROVISIONS

Article 17

When this regulation starts to be enacted, the regulation of Head of National Agency of Drug and Food Control, Number HK.00.05.1.3459, 2005, on Importation Control of Raw Drug Substances is revoked and declared invalid.

Article 18

This Regulation comes into force on the date of enacted.

For public recognizion, order the enactment of this regulation by placing it in the Official Gazette of the Republic of Indonesia