



**THE INDONESIAN FOOD AND DRUG AUTHORITY  
OF THE REPUBLIC OF INDONESIA**

**DISCLAIMER:**

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**REGULATION OF THE CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG  
AUTHORITY THE REPUBLIC OF INDONESIA  
NUMBER 27 OF 2018**

**ON**

**PUBLIC SERVICE STANDARDS WITHIN THE SCOPE OF  
THE INDONESIAN FOOD AND DRUG AUTHORITY**

**BY THE BLESSINGS ALMIGHTY GOD**

**THE CHAIRPERSON OF THE INDONESIAN FOOD AND DRUG AUTHORITY,**

- Considering:
- a. whereas provisions regarding public service standards within the Indonesian Food and Drug Authority as regulated in the Regulation of The Chairperson of the Indonesian Food and Drug Authority Number 39 Year 2013 regarding Public Service Standards Within the Scope of The Indonesian Food and Drug Authority, as amended by the Regulation of The Chairperson of the Indonesian Food and Drug Authority Number 15 Year 2016, need to be adapted to the necessity of accelerating public services within the scope of the Indonesian Food and Drug Authority;
  - b. whereas based on the considerations as meant in point a, it is deemed necessary to stipulate a Regulation of the Indonesian Food and Drug Authority regarding the Public Service Standards Within the Scope of The Indonesian Food and Drug Authority.

- Bearing in mind:
1. Law Number 5 Year 1997 on Psychotropic Drugs (State Gazette of the Republic of Indonesia Year 1997 Number 10, Supplement to State Gazette of the Republic of Indonesia Number3671);
  2. Law Number 8 Year 1999 on Consumer Protection (State

Gazette of the Republic of Indonesia Year 1999 Number 42, Supplement to State Gazette of the Republic of Indonesia Number 3821);

3. Law Number 25 Year 2009 on Public Services (State Gazette of the Republic of Indonesia Year 2009 Number 112, Supplement to the State Gazette of the Republic of Indonesia Number 5038);
4. Law Number 35 Year 2009 on Narcotics (State Gazette of the Republic of Indonesia Year 2009 Number 143, Supplement to State Gazette of the Republic of Indonesia Number 5062);
5. Law Number 36 Year 2009 on Health (State Gazette of the Republic of Indonesia Year 2009 Number 144, Supplement to State Gazette of the Republic of Indonesia Number 5063);
6. Law Number 18 Year 2012 on Food (State Gazette of the Republic of Indonesia Year 2012 Number 227, Supplement to State Gazette of the Republic of Indonesia Number 5360);
7. Government Regulation Number 72 Year 1998 on Safety of Pharmaceutical Preparations and Health Equipment (State Gazette of Republic of Indonesia Year 1998 Number 138, Supplement to State Gazette of the Republic of Indonesia Number 3781);
8. Government Regulation Number 69 Year 1999 on Food Labels and Advertisements (State Gazette of the Republic of Indonesia Year 1999 Number 313, Supplement to State Gazette of the Republic of Indonesia Number 3867);
9. Government Regulation Number 28 Year 2004 on Food Safety, Quality and Nutrition (State Gazette of the Republic Indonesia Year 2004 Number 107, Supplement to State Gazette of the Republic of Indonesia Number 4244);
10. Government Regulation Number 44 Year 2010 on Pharmaceutical Precursors (State Gazette of the Republic of Indonesia Year 2010 Number 60, Supplement to State Gazette of the Republic of Indonesia Number 5126);
11. Government Regulation Number 96 Year 2012 on Implementation of the Law Number 25 Year 2009 on Public Services (State Gazette of the Republic of Indonesia Year

- 2009 Number 215, Supplement to State Gazette of the Republic of Indonesia Number 5357);
12. Government Regulation Number 40 Year 2013 on Implementation of Law Number 35 Year 2009 on Narcotics (State Gazette of the Republic of Indonesia Year 2013 Number 96, Supplement to State Gazette of the Republic of Indonesia Number 5419);
  13. Government Regulation Number 32 Year 2017 on The Types and Rate on Types of Non-Tax State Revenue at the Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia Year 2017 Number 198, Supplement to State Gazette of the Republic of Indonesia Number 6116);
  14. Presidential Regulation Number 80 Year 2017 on the Indonesian Food and Drug Authority (State Gazette of the Republic of Indonesia Year 2017 Number 180);
  15. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.00.05.41.1381 Year 2005 on Management of Food Supplement Registration;
  16. Regulation of The Chairperson of the Indonesian Food and Drug Authority Number HK.00.05.41.1384 Year 2005 on the Criteria and Management for Registration of Traditional Medicines, Standardized Herbal Medicine and Phytopharmaceuticals;
  17. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.04.1.33.12. 11.09937 Year 2011 on Procedure for Certification of Good Manufacturing Practice for Medicines (Official Gazette of the Republic of Indonesia Year 2011 Number 397);
  18. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 35 Year 2013 on Procedure for Certification of Good Manufacturing Practice for Traditional Medicines (Official Gazette of the Republic of Indonesia Year 2013 Number 907);
  19. Regulation of the Minister of Administrative and Bureaucratic Reform Number 15 Year 2014 on Guidelines for Service Standards (Official Gazette of the Republic of Indonesia Year 2014 Number 615);

20. Regulation of the Head of the National Agency of Drug and Food Control Number 21 Year 2015 on Approval of Clinical Trials (Official Gazette of the Republic of Indonesia Year 2015 Number 1987);
21. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 32 Year 2013 on the Requirements and Procedure for Requesting a Review of Control in Order to Import and Export Narcotics, Psychotropic Drugs, and Pharmaceutical Precursors (Official Gazette of the Republic of Indonesia Year 2013 Number 729) as amended by the Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 20 Year 2016 regarding Amendment to the Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 32 Year 2013 on the Requirements and Procedure for Requesting a Review of Control in Order to Import and Export Narcotics, Psychotropic Drugs, and Pharmaceutical Precursors (Official Gazette of the Republic of Indonesia Year 2016 Number 1143);
22. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 25 Year 2017 on Procedure for Certification of Good Methods of Drug Distribution (Official Gazette of the Republic of Indonesia Year 2017 Number 1693);
23. Regulation of the Indonesian Food and Drug Authority Number 26 Year 2017 regarding the Organization and Working Procedures at the National Agency of Drug and Food Control (Official Gazette of the Republic of Indonesia Year 2017 Number 1745);
24. Regulation of the Indonesian Food and Drug Authority Number 27 Year 2017 on Registration of Processed Foods (Official Gazette of the Republic of Indonesia Year 2018 Number 23);
25. Regulation of the Indonesian Food and Drug Authority Number 29 Year 2017 on Control Over the Import of Drugs and Foodstuff into Indonesia (Official Gazette of the Republic of Indonesia Year 2017 Number 1843);

26. Regulation of the Indonesian Food and Drug Authority Number 30 Year 2017 on Control Over the Import of Drugs and Foodstuff into Indonesia (Official Gazette of the Republic of Indonesia Year 2017 Number 1843);
27. Regulation of the Indonesian Food and Drug Authority Number 12 Year 2018 on the Organization and Working Procedure of the Technical Implementing Units Within the Indonesian Food and Drug Authority (Official Gazette of the Republic of Indonesia Year 2018 Number 784);

HAS DECIDED:

To stipulate: REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY ON PUBLIC SERVICE STANDARDS WITHIN THE SCOPE OF THE INDONESIAN FOOD AND DRUG AUTHORITY.

## **CHAPTER I GENERAL PROVISIONS**

### Article 1

In this Agency Regulation, what is meant by

1. Service Standards are the benchmark used as a guide for providing services and a reference in assessing the quality of services as the obligation and commitment of the Indonesian Food and Drug Authority in order to have good quality services that are fast, easy, affordable, and measured.
2. Public Services are an activity or series of activities to fulfil the need of serving the community in order to provide drug and food control in accordance with the prevailing laws and regulations, in the form of administrative and technical services, both directly and indirectly.
3. Public Service Information System, to be referred to as the Information System, is a series of activities which include storing and managing information manually or electronically to be conveyed to the people.
4. Organizing Unit is a work unit equivalent to Echelon II in the Indonesian Food and Drug Authority and Technical Implementing Unit in the scope of the Indonesian Food and Drug Authority.
5. Public Servant, is an official, employee, officer, and any person working in the organizing unit who is assigned to perform an action or series of

- actions as a public service.
6. Service Announcement is a written statement containing all the details of the obligations and promises in the Service Standard.
  7. Applicant is any person who submits a request for public service within the scope of the Indonesian Food and Drug Authority.
  8. Any Person is an individual or a business entity, either in the form of a legal entity or not (institution).
  9. Head of Agency is the Head of the Indonesian Food and Drug Authority.
  10. Day is a work day.

## **CHAPTER II**

### **SCOPE OF THE REGULATION**

#### Article 2

The scope of this Agency Regulation includes:

- a. providing public services;
- b. guarantee of services;
- c. guarantee of security and safeness in the services;
- d. handling complaints; and
- e. evaluation of the performance.

## **CHAPTER III**

### **PUBLIC SERVICES**

#### Part One

#### Service Performance

#### Article 3

The Indonesian Food and Drug Authority organizes and provides public services for drug and food control.

#### Article 4

- (1) The types of public service provided by the Indonesian Food and Drug Authority as meant in Article 3 include applications/request for:
  - a. registration of drugs other than the initial registration of a new drug/medicine by a pharmaceutical company that has made its investment in Indonesia, registration of newly developed drugs, and initial registration of first generic medicines invested in Indonesia,

- and clinical trials;
  - b. registration of quasi-drugs;
  - c. approval to conduct pre-clinical/clinical trials, manufacture of traditional medicines, health supplements, and cosmetics;
  - d. assessment regarding fulfillment of requirements for Good Manufacturing Practice (GMP) for medicines, facilities for manufacture of import drugs;
  - e. issuing approval to use medicine production facilities together with non-medicine production facilities;
  - f. issuing approval to use traditional medicine production facilities together with quasi-drugs, cosmetics, and processed foods;
  - g. issuing the Certificate of GMP for Export;
  - h. approval of designs for advertisement of drugs, traditional medicines, health supplements, quasi drugs, and processed foods;
  - i. import of drugs, biological products/vaccine, traditional medicine, health supplements, cosmetics and processed foods through a Special Channel Mechanism or *Special Access Scheme (SAS)*;
  - j. issuing a Letter of Recommendation for Approval to Import Traditional Medicines, Health Supplements, and Cosmetics;
  - k. issuing a Letter of Recommendation to Obtain Recognition as Importer Producer of Hazardous Material;
  - l. examining the safety, quality, nutrition, benefit, and labels for processed foods;
  - m. examining the safety of genetically modified foods (GMF);
  - n. approval for clinical trials to be conducted on processed foods;
  - o. testing drugs and foods, and calibration of laboratory equipment;
  - p. request for reference material and test animals;and
  - q. information services and handling complaints from the community.
- (2) The types of public service and the units organizing the public services are listed in Attachment I which is an inseparable part of this Agency Regulation.

#### Article 5

- (1) Any Application for Public Services within the scope of the Indonesian Food and Drug Authority which is a request for listing/registration/notification, testing, as regulated in Article 3 must be performed by the Applicant himself.

- (2) The applicant for public services as meant in clause (1) is the management of the company/industry that holds the required license or permit according to the provisions of the laws and regulations.
- (3) The management of the company/industry as meant in clause (2) may confer powers to an employee of the said company/industry to submit an application for public service in the scope of the Indonesian Food and Drug Authority.
- (4) The employee as meant in clause (3) must have adequate knowledge and competence pursuant to the public service requested.
- (5) The management of the company/industry as meant in clause (2) is forbidden to use a service bureau or go-between in the process of putting forth a request for public services to the Indonesian Food and Drug Authority.

#### Article 6

- (1) The providing of public services as meant in Article 3 shall be performed by the Public Servant.
- (2) In providing the public services, the Public Servant as meant in clause (1) shall issue a guarantee for service in conformity with the provisions in the Public Service Standards within the Indonesian Food and Drug Authority, as contained in Attachment I which is an inseparable part of this Agency Regulation.
- (3) The service standards as meant in clause (2) shall be adjusted dynamically to the need for public services, developments in science and technology and must be in accordance with the provisions of the current laws and regulations.

#### Article 7

- (1) The types of public service meant in Article 4 clause (1) can be performed using an *online* system.
- (2) Public services using an *online* system as meant in clause (1) shall be performed in stages.

#### Article 8

- (1) In order to provide the public services, the public servant must have adequate competence in accordance with the fixed standard.
- (2) Besides fulfilling the provisions as meant in clause (1), the public servant must meet the following requirements:

- a. be fair and non-discriminating;
- b. thorough;
- c. polite and friendly;
- d. firm, reliable, and does not drag on when making decisions;
- e. professional;
- f. does not complicate or make things difficult;
- g. shall obey orders made by his superior that are fair and reasonable;
- h. uphold the values of accountability and integrity of the implementing institution;
- i. shall not give out information or reveal any document that must be kept confidential in compliance with the provisions of the current laws and regulations;
- j. be open-minded and take the necessary steps to avoid a conflict of interests;
- k. shall not misuse the means and infrastructures as well as the facilities for public services;
- l. shall not give out wrong or misleading information when responding to a request for information and shall be proactive in meeting the interests of the people;
- m. shall not misuse any information, position/post, and/or authority that he has;
- n. conform with appropriateness; and
- o. will not deviate from the procedure.

#### Article 9

- (1) The Head of the Agency and the Organizing Unit shall make a Service Announcement.
- (2) The Service Announcement as meant in clause (1) is made in order to apply the Service Standards that are applicable within the scope of the Indonesian Food and Drug Authority.
- (3) The Service Announcement must be publicized widely, clearly and openly to the people.
- (4) The Service Announcement as meant in clause (2) uses the format given in Attachment II which is an inseparable part of this Agency Regulation.

Part Two  
Public Service Information

Article 10

- (1) An Information System should be kept to provide information as support for organizing public services within the scope of the Indonesian Food and Drug Authority.
- (2) In the framework of providing information as support for organizing public services, it is necessary to maintain an Information System.
- (3) The Information System as meant in clause (1) contains all information regarding the public services provided within the scope of the Indonesian Food and Drug Authority.
- (4) Public Service Information as meant in clause (2) shall be delivered through the website and/or other appropriate media.

Part Three  
Internal Control

Article 11

- (1) Internal control in the implementation of public services shall be carried out in accordance with the provisions of the current laws and regulations.
- (2) The internal control as meant in clause (1) shall be implemented by the direct superior and/or by the Main Inspectorate of the Indonesian Food and Drug Authority.

**CHAPTER IV**  
**SERVICE GUARANTEE**

Article 12

- (1) The public services provided within the scope of the Indonesian Food and Drug Authority shall be carried out in conformity with the service guarantee based on the framework and procedures consisting of:
  - a. type of service;
  - b. time of completion;
  - c. cost/rate; and
  - d. service product.

- (2) The time of completion as meant in clause (1) point b is the longest time set to produce the service product after the document is declared to be complete and correct.
- (3) Cost/rate as meant in clause (1) point c is the cost that must be paid as Non-Tax State Revenue in compliance with the provisions of the current laws and regulations.
- (4) Payment of the cost/rate must be made before the application or request for public service is processed.
- (5) If the application as meant in clause (4) is rejected, the costs already paid cannot be withdrawn/retrieved.

## **CHAPTER V**

### **SECURITY GUARANTEE AND SAFETY OF SERVICES**

#### Article 13

The applicant who submits a request for public service within the scope of the Indonesian Food and Drug Authority will be treated with courtesy so that he feels safe, free from danger and doubts.

## **CHAPTER VI**

### **COMPLAINTS MANAGEMENT**

#### Article 14

- (1) The Applicant can submit a complaint or criticism regarding the implementation of public services within the scope of the Indonesian Food and Drug Authority.
- (2) Complaints as meant in clause (1), may consist of:
  - a. providing information about indications that there is an irregularity or misuse of authority by the Public Servant, which is causing losses to the Applicant/State; and
  - b. request for clarification, confirmation or complaints related to the irregularity in public services within the scope of the Indonesian Food and Drug Authority.
- (3) Complaints as meant in clause (2), will be conveyed to the Head of the Agency through the Main Inspectorate of the Indonesian Food and Drug Authority.
- (4) The complaints as meant in clause (2) point b can also be conveyed

directly to the Organizing Unit.

#### Article 15

Complaints regarding the public services provided by the Indonesian Food and Drug Authority should be made according to the procedures given in Attachment III which is an inseparable part of this Agency Regulation.

### **CHAPTER VII PERFORMANCE EVALUATION**

#### Article 16

- (1) Evaluation on the performance of public services will be carried out periodically and continuously.
- (2) The evaluation on performance as meant in clause (1), will be done each year by conducting a survey on customers' satisfaction.

### **CHAPTER VIII TRANSITIONAL PROVISIONS**

#### Article 17

Any application or request for public services that was submitted before the enactment of this Agency Regulation will still be processed based on the Regulation of the Chairperson of the Indonesian Food and Drug Authority Number T39 Year 2013 on Public Service Standards Within The Scope of the Indonesian Food and Drug Authority which was amended by the Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 15 Year 2016 (Official Gazette of the Republic of Indonesia Year 2016 Number 931) on Amendment to the Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 39 Year 2013 on Public Service Standards Within The Scope of the Indonesian Food and Drug Authority.

### **CHAPTER IX CLOSING PROVISIONS**

#### Article 18

At the time this Authority Regulation becomes effective, the Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 39 Year 2013 regarding Public Service Standards Within The Scope of the Indonesian Food

and Drug Authority as amended by the Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 15 Year 2016 regarding Amendment to the Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 39 Year 2013 regarding Public Service Standards Within The Scope of the Indonesian Food and Drug Authority (Official Gazette of the Republic of Indonesia Year 2016 Number 931) will be revoked and declared null and void.

#### Article 19

This Authority Regulation shall become valid and effective on the date of its enactment.

In order that all shall be aware thereof, has ordered the enactment of this Agency Regulation through its placement in the Official Gazette of the Republic of Indonesia.

Stipulated in Jakarta

On 23 August 2018

CHAIRPERSON OF THE INDONESIAN FOOD  
AND DRUG AUTHORITY

*signed*

PENNY K. LUKITO

Enacted in Jakarta

On 23 August 2018

DIRECTOR GENERAL OF LEGISLATION  
MINISTRY OF LAW AND HUMAN RIGHTS OF  
THE REPUBLIC OF INDONESIA,

*signed*

WIDODO EKATJAHJANA

**ATTACHMENT I:**

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY  
NUMBER 27 YEAR 2018  
REGARDING  
PUBLIC SERVICE STANDARDS WITHIN THE SCOPE OF  
THE INDONESIAN FOOD AND DRUG AUTHORITY

**TYPES OF PUBLIC SERVICE WITHIN THE SCOPE OF THE INDONESIAN  
FOOD AND DRUG AUTHORITY**

The types of Public Service provided by the Indonesian Food and Drug Authority, consist of applications for:

| <b>NO.</b> | <b>TYPES OF PUBLIC SERVICE STANDARDS</b>   | <b>INFORMATION</b>  |
|------------|--|---|
| 1          | Registration of drugs other than the initial registration of a new drug by a pharmaceutical company that has made its investment in Indonesia, the registration of newly developed drugs, and initial registration of first generic medicines invested in Indonesia and clinical trials. | <ul style="list-style-type: none"><li>- Organizing Unit at the Directorate for Drug Registration:</li><li>- Sub-Attachment I.1</li></ul>  |
| 2          | Registration of quasi-drugs  | <ul style="list-style-type: none"><li>- Organizing Unit at the Directorate for Registration of Traditional Medicines, Health Supplements, and</li><li>- Sub-attachment I.2</li></ul>            |
| 3          | Approval to conduct pre-clinical/ clinical trials, manufacture of traditional medicines, health supplements, and cosmetics   | <ul style="list-style-type: none"><li>- Organizing Unit at the Directorate for Registration of Traditional Medicines, Health Supplements, and Cosmetics:</li><li>- Sub-attachment I.3</li></ul> |

| <b>NO.</b> | <b>TYPES OF PUBLIC SERVICE STANDARDS</b>  | <b>INFORMATION</b>   |
|------------|---|--|
| 4          | Assessment regarding the fulfillment of requirements for Good Manufacturing Practice (GMP) for medicines, facilities for manufacture of import drugs; | <ul style="list-style-type: none"> <li>- Organizing Unit at the Directorate for Control on Production of Drugs, Narcotics, Psychotropic Drugs, and Precursors:</li> </ul>  |
| 5          | Issuing approval to use medicine production facilities together with non-medicine production facilities;  | <ul style="list-style-type: none"> <li>- Sub-attachment I.4</li> <li>- Sub-attachment I.5</li> </ul>   |
| 6          | Issuing approval to use traditional medicine production facilities together with those for quasi-drugs, cosmetics, and processed foods;               | <ul style="list-style-type: none"> <li>- Organizing Unit at the Directorate for Control of Traditional Medicines and Health Supplements</li> <li>- Sub-attachment I.6</li> </ul>   |
| 7          | Issuing the Certificate of GMP (Good Manufacturing Practice) for Export;  | <ul style="list-style-type: none"> <li>- Organizing Unit at the Directorate for Control on Production of Drugs, Narcotics, Psychotropic Drugs, and Precursors</li> <li>- Sub-attachment I.7</li> </ul>   |
| 8          | Approval of advertisement designs for drugs, traditional medicines, health supplements, quasi drugs, and processed foods;                             | <ul style="list-style-type: none"> <li>- Organizing Units at the</li> <li>1) Directorate for Control of Safety, Quality and the Export Import of Drugs, Narcotics, Psychotropic Drugs, and Addictive Substances</li> <li>2) Directorate for Registration of Traditional Medicines, Health Supplements, and Cosmetics</li> <li>3) Directorate for Registration of Processed Foods.</li> <li>- Sub-attachment I.8</li> </ul> |

| <b>NO.</b> | <b>TYPES OF PUBLIC SERVICE STANDARDS</b>  | <b>INFORMATION</b>  |
|------------|---|---|
| 9          | Import of drugs, biological products/vaccine, traditional medicine, health supplements, cosmetics and processed foods through a Special Channel Mechanism or <i>Special Access Scheme (SAS)</i> ; | <ul style="list-style-type: none"> <li>- Organizing Units at the</li> <li>1) Directorate for Control of Safety, Quality and the Export Import of Drugs, Narcotics, Psychotropic Drugs, and Addictive Substances</li> <li>2) Directorate for the Registration of Traditional Medicines and Health Supplements</li> <li>3) Directorate for Control of Cosmetics</li> <li>4) Directorate for Control of Low and Medium Risk Foods</li> <li>5) Directorate for Control of High Risk Foods and New Technology</li> <li>- Sub-attachment I.9</li> </ul> |
| 10         | Issuing a Letter of Recommendation for Approval to Import Traditional Medicine, Health Supplements, and Cosmetics;  | <ul style="list-style-type: none"> <li>- Organizing Unit at the</li> <li>1) Directorate for Control of Traditional Medicines and Health Supplements</li> <li>2) Directorate for Control of Cosmetics</li> <li>- Sub-attachment I.10</li> </ul>  |
| 11         | Letter of Recommendation to Obtain Recognition as Importer Producer of Hazardous Material;  | <ul style="list-style-type: none"> <li>- Organizing Unit at the Directorate for Control of Cosmetics</li> <li>- Sub-attachment I.11</li> </ul>  |
| 12         | Examining the safety, quality, nutrition, benefit, and labels for processed foods;  | <ul style="list-style-type: none"> <li>- Organizing Unit at the Directorate for Standardization of Processed Foods</li> <li>- Sub-attachment I.12</li> </ul>  |

| <b>NO</b> | <b>TYPES OF PUBLIC SERVICE STANDARDS</b>                         | <b>INFORMATION</b>  |
|-----------|--|---|
| 13        | Examining the safety of genetically modified foods (GMF);        | - Organizing Unit at the Directorate for the Standardization of Processed Foods<br>- Sub-attachmentI.13<br>Sub-attachmentI.14   |
| 14        | Approval for conducting clinical trials on processed foods       |   |
| 15        | Testing drugs and foods, and calibration of laboratory equipment | - Organizing Units at the<br>1) National Center for Development of Drug and Food Testing<br>2) All Centers/Drug and Food Control Centers<br>- Sub-attachment I.15<br>Sub-attachmentI.16 |
| 16        | Request for reference material and test animals                  |   |
| 17        | Providing information and handling complaints from the community | - Organizing Unit at the<br>1) Public Relations and Managerial Strategy Support<br>2) All Centers / Drug and Food Control Center<br>- Sub-attachment I.17                               |

CHAIRPERSON OF THE INDONESIAN FOOD  
AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

**ATTACHMENT II:**

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY  
NUMBER 27 YEAR 2018  
REGARDING  
PUBLIC SERVICE STANDARDS WITHIN THE SCOPE OF  
THE INDONESIAN FOOD AND DRUG AUTHORITY

**SERVICE ANNOUNCEMENT**

THE INDONESIAN FOOD AND DRUG  
AUTHORITY/**ORGANIZING UNIT**  
**NUMBER : .....**

I , (the Chairperson of Authority/Organizing Unit for Public Services) do herewith declare :

That I am capable of providing the services in accordance with the fixed standards for service and if I am unable to do this, then I am prepared to accept the sanction imposed by the law.

This statement is made by:

Signature :

Position and Name :

CHAIRPERSON OF THE INDONESIAN FOOD  
AND DRUG AUTHORITY,

signed

PENNY K. LUKITO

## **ATTACHMENT III :**

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY  
NUMBER 27 YEAR 2018  
REGARDING  
PUBLIC SERVICE STANDARDS WITHIN THE SCOPE OF  
THE INDONESIAN FOOD AND DRUG AUTHORITY

**HANDLING OF PUBLIC COMPLAINTS WITHIN THE SCOPE OF THE  
INDONESIAN FOOD AND DRUG AUTHORITY**

**CHAPTER I  
INTRODUCTION**

### **A. BACKGROUND**

For changes in the government paradigm - which is usually marked by demands made by the people for the realization of good governance - each process of running the government must be truly free from corrupt practices, collusion, and nepotism.

When public services can be performed well, it is an indication that the government's management has improved. On the other hand it also indicates that there was a change in the pattern of thinking that influenced changes for the better in the mental attitude and behavior of the government apparatus to become more oriented to public services.

No less important is that good public services can be effective for reducing or minimizing the possibility of corruption, collusion, and nepotism within all lines of public services, while also eliminating discrimination in providing the services.

In the implementation of public services, there should be some form of control by the people as the consumers, to help create a government that is clean and free from corruption, collusion, and nepotism. One of the ways that the people can apply control and which should be handled/managed efficiently and effectively is in the form of complaints submitted by the general public.

In order that public complaints can function effectively as a social control in the providing of public services, the handling of complaints received from the people should be quick, appropriate, effective, efficient, and of course, must be able to be accounted for.

For this it is necessary to establish guidelines to be used by the

Indonesian Food and Drug Authority in handling complaints from the people.

## **B. LEGAL BASIS**

1. Law Number 13 Year 2006 on Witness and Victim Protection;
2. Law Number 14 Year 2008 on Openness of Public Information;
3. Law Number 25 Year 2009 on Public Services;
4. Government Regulation Number 68 Year 1999 on Community Participation in Running the State;
5. Government Regulation Number 96 Year 2012 on Enforcement of the Law Number 25 Year 2009 on Public Services;
6. Presidential Regulation Number 76 Year 2013 on Handling Public Service Complaints;
7. Presidential Regulation Number 80 Year 2017 on the the Indonesian Food and Drug Authority;
8. Regulation of the State Minister for Administrative Reform Number PER/05/M.PAN/4/2009 on General Guidelines for the Government Agencies for Handling Public Complaints;
9. Regulation of the State Minister for Administrative Reform Number 13 Year 2009 on Guide to Improve the Quality of Public Services with Participation of the Community;
10. Regulation of the Chairperson of the the Indonesian Food and Drug Authority Number HK.03.1.23.08.11.07456 Year 2011 on Procedures for Public Information Service Within the Scope of the the Indonesian Food and Drug Authority;
11. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.23.12.11.1005 Year 2011 on the Managing and Follow-Up to Reports of Violation (*Whistleblowing*) within the scope of the Indonesian Food and Drug Authority;
12. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 14 Year 2014 on Organization and Working Procedure of the Technical Implementing Unit Within the Scope of the Indonesian Food and Drug Authority;
13. Regulation of the Minister for Administrative and Bureaucratic Reform Number 15 Year 2014 on a Guide for Service Standards;
14. Regulation of the Minister for Administrative and Bureaucratic Reform Number 24 Year 2014 on Guidelines for Managing Public Service Complaints on a National Scale;

15. Regulation of the Minister for Administrative and Bureaucratic Reform Number 3 Year 2015 on a Road Map for Developing a System for Managing Complaints Regarding Public Service on a National Scale;
16. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 6 Year 2017 on the List of Public Information Exempted Within the Scope of the Indonesian Food and Drug Authority;
17. Regulation of the Indonesian Food and Drug Authority Number 26 Year 2017 on the Organization and Working Procedures of the Indonesian Food and Drug Authority;
18. Decree of the Minister for Administrative and Bureaucratic Reform Number KEP/118/M.PAN/8/2004 on General Guidelines for Handling Public Complaints, for the Government Agencies.

### **C. GOALS**

1. To ensure that complaints from the people are handled well, that is correctly, effectively and efficiently.
2. To ensure that the handling of public complaints is better coordinated and uses the same mechanism of handling.
3. Using the complaints from the people as a form of social control towards the running of the government and its delivery of public services.
4. To encourage the realization of Good Governance which is free from corruption, collusion, and nepotism (CCN).

### **D. TARGETS**

1. Completion in resolving the complaints and grievances of the people that is quick, accurate, orderly, and can be accounted for to the community in accordance with the laws and regulations in effect.
2. Achieving similarity in perception and in the mechanism used for handling the people's complaints.
3. Creating good coordination among the government agencies in handling the people's complaints.
4. Providing good community services by the government apparatus in the context of handling the people's complaints.

## **E. MEANINGS**

1. **State Apparatus** consists of all the agencies and state officials, and governments which comprise both state and government apparatus, and servants of the State and of the people, who are assigned and responsible for running the country and will always serve and be loyal to the interests, values, and ideals of the nation and the country based upon *Pancasila* and the 1945 Constitution.
2. **Government Apparatus** are the government devices that carry out the general tasks of the government as well as community service, at both central and regional levels.
3. **Government Internal Control Apparatus**, henceforth shall be referred to as APIP (*Aparat Pengawasan Intern Pemerintah*), is the institution/work unit within the scope of the Government Agency whose task and function is to conduct functional control over the running of the government, including the Internal Control Unit (*SPI/Satuan Pengawasan Intern*).
4. **Government Agencies** is a collective term which includes the Presidential Secretariat, Coordinating Ministry, Departments, State Ministry, Attorney General's Office, Indonesian Army Headquarters, Indonesian Police Headquarters, Non-Departmental Government Institutions, Secretariat of State Higher Institutions, Secretariat of Other Institutions, Provincial/ District/City Governments including the government-owned companies (BUMN/BUMD, BHMN/BHMD) and other business entities/legal entities owned by the State and other government institutions at both central and regional levels.
5. **Clarification** is the process of clearing up or an activity that will clear up or give an explanation about the problem that was submitted as a complaint in its true proportion to the source of complaint and related institution.
6. **Confirmation** is the process of obtaining affirmation regarding the member of the community identified, whether an individual, group, or institution, if possible, and including the problem reported.
7. **Community** consists of all the parties, citizens and residents as an individual, or group, or legal entity that receives the benefit of the public service, directly or indirectly.
8. **Community Participation** is the active role of the community in participating to create state officials who are clean and free from

corruption, collusion, and nepotism.

9. **Complainant** is any party, both citizen and resident, as an individual, group or legal entity that submits a complaint to the public service complaint manager.
10. **State Officials** can be the leaders and members of a state institution as meant in the 1945 Constitution, and other state officials as determined by the law.
11. **Service** consists of all activities performed by the provider of services in the effort to meet the needs of the recipient or to fulfill the provisions of the laws and regulations.
12. **Handling Public Complaints** is a process consisting of receiving, recording, reviewing, proving (through confirmation, clarification, research, investigation), reporting, recommending, archiving, taking follow-up action, and monitoring the complaint.
13. **Public Complaint** is the form of social control by the general public to the Main Inspectorate of the Indonesian Food and Drug Authority or to the unit organizing the services, which can be allegations of irregularity and misuse of authority, request for clarification or confirmation of the service.
14. **Complaint With Control** is a complaint made by anyone in the community which contains information or indications that there are irregularities, deviation or misuse of authority and power by the state apparatus, which has caused losses to the people / state, in running the government.
15. **Complaint Without Control** is a complaint made by anyone in the community which contains information such as suggestions, constructive criticism, and other such information that will be useful for improving the quality of the government's management and its public services.
16. **Functional Control**, is the control by apparatus on the government functions, both internal and external, with regard to implementation of the government's general tasks and public service, to ensure that it is according to plan and complies with the provisions of the current laws and regulations in effect.
17. **State Administrators** are officials who have executive, legislative, or judicative functions, and other officials whose function and main tasks are related to running the state in accordance with the

provisions of the current laws and regulations in effect.

18. **Public Complaints Officer** is the officer appointed to manage the administrative affairs relating to complaints.
19. **Institution Leader** is the Employee Development Official at central or regional level.
20. **Community Control**, is the control by the people over the management of the government.
21. **Handling of public complaints** are activities which consist of receiving, recording, reviewing, distributing, confirmation, clarification, research, investigation, reporting, follow-up action, and archiving.
22. **Investigation** is the process of identifying the problem, reviewing, and evaluating the evidence which is done independently, objectively, and professionally based on the set standards, to judge whether the complaint can be justified.
23. **Person Reporting** is the individual, or social group that submits a complaint to the specific government institution.
24. **Referral** is an activity of the public complaints department to forward the complaint to the relevant work unit that is authorized to handle the complaint, make corrections, and take legal action in accordance with its position, main tasks, function and authority based on the provisions of the current laws and regulations in effect.
25. **Status: Completed** is when the authorized institution/work unit has issued a report regarding the result of investigation on the complaint.
26. **Defendant** is the apparatus of the Indonesian Food and Drug Authority alleged to have deviated from or violated the standards related to performing its tasks or in connection with its position as a civil servant of the State.
27. **Follow Up** is a further activity that must be carried out by the head of the institution or the authorized work unit by recommendation or suggestion of the control apparatus based on the result of research or investigation on a certain case reported by the people.

## **F. PRINCIPLES IN THE HANDLING OF PUBLIC COMPLAINTS**

1. **Legal Certainty**, that is prioritizing the current laws and regulations as the basis in handling public complaints;

2. **Transparency**, is to have an open attitude and give opportunity to the general public to exercise their right to get information that is accurate, honest and non-discriminative towards the handling of public complaints based on a clear mechanism and procedure;
3. **Coordination**, is to have good cooperation among the authorized officials and the relevant government apparatus based on the applicable mechanism and working procedures;
4. **Effectiveness and Efficiency**, means being right on target, saving one's energy, time and costs;
5. **Accountability**, is that it can be accounted for to the people, in terms of process as well as follow-up actions;
6. **Objectivity**, is based on facts or evidence without being influenced by prejudice, interpretation, personal interests, group interests or the interests of a certain party;
7. **Proportionality**, means that priority is placed on the interest of implementing tasks and upholding authority with a balanced observance of other legitimate interests;
8. **Confidentiality**, is to maintain the confidentiality of data and information in compliance with the provisions of the current laws and regulations in effect, except when there is a legal or professional right or obligation to disclose said data and/or information;
9. **Fair**, is to handle the public complaints without discriminative treatment towards the person reporting (complainant);
10. **Independent**, is to manage the public complaints without intervention from any party whatsoever or any person whomsoever;

## **CHAPTER II**

### **SCOPE OF COMPLAINTS**

Public complaints can be grouped into 3 (three) categories as follows:

1. Public complaints that contain information or a report that there is indication of deviation or misuse of authority by the apparatus of the Indonesian Food and Drug Authority that could cause losses to the community/state in the context of implementing *good governance*.
2. Public complaints that contain a request for clarification, confirmation, or a complaint related to irregularity in the public services provided by the

Indonesian Food and Drug Authority, production (quality), distribution (illegal means and illegal products) of drugs and food products under the control of the Indonesian Food and Drug Authority.

3. Public complaints where the identity of the complainant or person reporting is not clear and or there is no data that is reliable and supports the information submitted and or the complaint is actually the desire of the person reporting that normatively is not in accordance with the provisions of the current laws and regulations, and it is impossible for the government to fulfill such desire – then further handling will not be needed, and it will be enough to record the complaint as documentation / archive.

### **CHAPTER III**

#### **PUBLIC COMPLAINTS ADMINISTRATION**

##### **A. RECEIVING COMPLAINTS FROM THE GENERAL PUBLIC**

The submission of complaints that contain elements of control and complaints that do not contain control can be done through:

- a) Reporting through application of the Whistleblowing System in the sub-site Bureaucratic Reform of the Indonesian Food and Drug Authority <http://rb.pom.go.id/modul/wbs/faq>
- b) Direct Submission.  
The person reporting can come directly to the complaints officer at the Main Inspectorate of the Indonesian Food and Drug Authority, Gedung A, Jl. Percetakan Negara Number 23, Jakarta Pusat.
- c) Letter.  
The letter should be addressed to the Main Inspector of the Indonesian Food and Drug Authority, Gedung A, Jl. Percetakan Negara Number 23, Jakarta Pusat.
- d) Email.  
*Email address:*  
[tuirtamabadanpom@gmail.com](mailto:tuirtamabadanpom@gmail.com)  
[bagiantu.ittamabpom@gmail.com](mailto:bagiantu.ittamabpom@gmail.com)  
[mtuinspektorat1bpom@gmail.com](mailto:mtuinspektorat1bpom@gmail.com)  
[mtuinspektorat2bpom@gmail.com](mailto:mtuinspektorat2bpom@gmail.com)
- e) Telephone/facsimile

## **B. RECORDS**

Records should be made according to the procedures of administration used in the Indonesian Food and Drug Authority, manually or using a computer application system appropriate for the facilities available.

Complaints from the community that are received directly, or written/by letter, and through the electronic media and print media, shall be recorded as follows:

1. Data on the complaint letter, includes:
  - a. Number and date of the agenda
  - b. Date of the complaint letter
  - c. Category
  - d. Subject of complaint
2. Identity of the complainant/person reporting, includes:
  - a. Name
  - b. Address
  - c. Occupation
  - d. District/City
  - e. Province
  - f. Category of complainant/person reporting
3. Identity of the defendant/person reported, includes:
  - a. Name
  - b. NIP/NRP
  - c. Address
  - d. Position
  - e. Institution reported  
Category of the Institution
4. Location of the case, includes:
  - a. District/City
  - b. Province
  - c. Country

## **C. REVIEW**

The steps in reviewing the material of the complaint should, at the least, include the following activities:

1. Formulate the core problem;

2. Relate the material of complaint with the relevant regulations;
3. Examine the documents and/or information that are already available in their connection with the material of the complaint just received;
4. Determine the result of reviewing the complaint to be used in the next step of handling.

The results of reviewing public complaints can be grouped into 2 (two) categories, namely:

1. Complaints with element of control:
  - a. When the substance/material of the complaint is logical and adequate and the identity of the person reporting is clear and supported by initial evidence, then an investigation must be made to prove the accuracy of the information received;
  - b. When the substance/material of the complaint is logical and adequate and supported by initial evidence, but the identity of the person reporting is not clear, then an investigation must be made to prove the accuracy of the information received;
  - c. When the substance/material of the complaint is not adequate and the identity of the person reporting is clear, then it is necessary to make clarification and confirmation before conducting an investigation;
  - d. When the substance of the problem is the same, and is being investigated or has been investigated, it will become additional information for the proving process.
2. Complaints Without Control:
  - a. When the substance/material of the complaint consists of suggestions, constructive criticism, and the like that can be useful for improving the running of the government and its public services, then it shall be kept as information or material for making decisions/determining policies;
  - b. When the substance/material of the complaint is illogical and is only the desire of the person reporting, which normatively is not in line with the laws and regulations in effect and it is impossible for the government to fulfill this desire, then it need not be processed further.

## **D. DISTRIBUTION**

Distribution is one of the activities of APIP (Government Internal Control Apparatus) that receives the complaints of the community and forwards them to the work units authorized to handle complaints, take corrective action and other legal action pursuant to their position, main tasks, function and authority based on the current laws and regulations in effect.

1. Distribution based on the reported object
  - a. Government apparatus

When the problems submitted are about irregularity, deviation and violations made by government apparatus, the distribution will be to APIP so that they can be immediately handled, with a copy to the Head of the Indonesian Food and Drug Authority for his attention.
  - b. Nongovernment apparatus

When the problems submitted are about irregularity, deviation and violations by non-government apparatus, the distribution will be to APIP with a copy to the Head of the Indonesian Food and Drug Authority.
2. When the problems involve state administrators and other persons who are linked to the corruption by the state administrators, and have attracted the attention of the community and are causing restlessness among the people, and/or involve losses to the state of at least Rp1,000,000,000.00(one billion rupiah), the distribution will be to APIP for immediate follow-up action.
3. In the context of protecting the person who made the report from parties who are not involved, APIP shall keep confidential and guard against all possibilities of finding out the identity of the person who made the report, such as not stating his identity in the distribution letter and covering his identity mentioned in the complaint letter that will be attached to the distribution letter.

If, in the process of proving the truth of the complaint, it is necessary to get information regarding the person who made the report, APIP may request the identity of said person to the work unit that distributed/sent him, with the obligation of keeping the identity of the person who reported, confidential.
4. Should there be a mistake in the address of distribution and/or the

attached distribution letter which is inappropriate, then APIP must immediately return all distribution documents to the work unit that distributed/sent them so that the proper corrections can be made.

5. Should there be a mistake in the destination of distribution which has no authority, then APIP must immediately redistribute to the work unit that is authorized to handle, with a copy to the related work unit so that it can be handled properly.

## **E. ARCHIVES**

Good arrangement or archiving of documents is meant to store the documents safely and make it easier and quicker to look for and retrieve the complaint documents when they are needed at any time. The storing of documents will be based on classification according to type of problem, the institution/work unit reported, time of reporting, and storage will be pursuant to the available facilities and in accordance with the applicable procedure of archiving.

The documents and complaint reports must be stored safely and when possible should use digital facilities in order to be easier to retrieve when they are needed. Archiving will be in the form of electronic data (*softcopy*). Any *hardcopy* data must be converted to *softcopy* and stored in the database.

Archives of the public complaint letters that contain elements of control and are confidential must be stored well and carefully. For requests of information from other parties (the community, non-governmental organizations, mass media, and others) that have no connection, the information that can be given out is only statistical data regarding the handling and not the substance of the case, except when the complaint letter has no element of control, such as a list of suggestions, requests for donation/assistance, etcetera.

## **CHAPTER IV**

### **PROVING THE PUBLIC COMPLAINT**

Public complaints that have an element of control must be resolved by proving the truth of the substance of the case through the following activities:

#### A. Investigation

##### 1. Further review.

Further review shall be done as follows:

- a. studying and formulating the problem;
- b. showing the result of formulation to the management of the institution, when the case is significant;
- c. declaring that the complaint implies there is a violation of the rules.

##### 2. Confirmation

Confirmation consists of:

- a. identifying the person reported (defendant);
- b. seeking additional information from other sources that have a connection with the problem being reported, as support material.

##### 3. Clarification

Clarification consists of:

- a. requesting explanations, both verbal or written, to those parties that have a connection with the problem reported;
- b. making an assessment of the problem reported, with reference to the current laws and regulations in effect;
- c. requesting documents that support the explanations given by the parties meant above.

The results from further reviews, confirmation and clarification of the public complaints will be a conclusion of whether or not an investigation should be made on the complaint / problem reported. If the results say it is not necessary to conduct an investigation because there is not enough evidence, then APIP shall inform the results to the person who reported the problem. When the result concludes that more intensive control should be made, the following matters should be observed:

1. Control activities refer to the system, procedure and provisions as well as the direction and policy of handling public complaints that are in place at each institution which receives complaints in order to obtain physical evidence, documental evidence, calculation evidence, clarification from experts, and or other evidence regarding the truth of the complaint.
2. Control should be thorough, fast, and easy and the results can be accounted for, using the following methods:
  - a. establishing /determining a team of competent auditors;
  - b. allocating a budget for control;
  - c. formulating a Work Program for Control which includes:
    - 1) reviewing the laws and regulations that are relevant to the complaint/problem reported;
    - 2) determining the method and procedure for control;
    - 3) determining the location and time needed;
    - 4) determining which parties should be asked for information;
    - 5) determining the validity and adequacy of the proof obtained;
    - 6) declaring the results of control.

#### B. Time for Completion

The handling of public complaints must be able to be completed within a period of at most 90 (ninety) days after the complaint letter is received by APIP, except when there are reasons that can be accounted for.

#### C. Reporting

1. The investigation report shall be made systematically, and should be brief, clear and accountable and contain the conclusion of the results of further review, confirmation, clarification, and investigation, with supporting data and recommendations for further action.
2. The results of investigating public complaints distributed by a government institution should be reported to the head of the distributing institution.
3. The results of investigating the public complaint shall be promptly delivered by APIP to:

- a. Head of the Work Unit reported (the defendant);
  - b. Head of the Indonesian Food and Drug Authority.
4. APIP is required to periodically report the developments in handling public complaints (every semester) to the Minister of Administrative and Bureaucratic Reform.

D. Protection of the Person Reporting and the Person Reported

During the process of proving the complaint, the Indonesian Food and Drug Authority must provide legal protection and fair treatment to both the person reporting the complaint and the person who is reported.

1. Protection of the Person Reporting

- a. The person reporting information about indications of deviation by the government apparatus/state apparatus during the process of proving a public complaint cannot be prosecuted by the law, both civil and criminal, for reports that will, are or have been given in accordance with the laws and regulations in effect.
- b. Persons giving information about indications of deviation by the government apparatus/state apparatus whose complaint has not yet been handled by the law enforcers, shall be given administrative protection while maintaining confidentiality of the person's identity.
- c. If the complaint has already been handled by the law enforcers and the person reporting must become a witness, then the person shall be entitled to be given protection in accordance with the laws and regulations in effect.

2. Protection of the Person Reported

- a. The Head of the Indonesian Food and Drug Authority is required to treat the person reported as not guilty until the results of review, confirmation, clarification and investigation can prove whether the complaint is valid or not.
- b. The Head of the Indonesian Food and Drug Authority must provide protection to the person reported by not imposing sanction of any kind in any form whatsoever without the support of valid evidence obtained from the reviews,

confirmation, clarification and investigation.

## **CHAPTER V**

### **RESULT OF HANDLING PUBLIC COMPLAINTS**

#### **A. Function of the Handling Results**

The results of handling public complaints can be used to:

1. Develop and increase the participation of the people in building up healthy social control towards the running of the government;
2. Become a trustworthy benchmark or barometer for the general public regarding the performance of government apparatus;
3. Build an image of government apparatus that are ethical, moral, professional, transparent, responsible and have '*esprit de corps*' in running the government and providing public service;
4. Improve and increase the effectiveness of an internal control system, including functional control, particularly in the field of public service and the prevention of corruption, collusion and nepotism;
5. Build up a sensitivity and increase the effectiveness of managerial functions particularly in improving the formulation of policies, planning, budgeting, implementation, and accountability reports at all levels of the government bureaucracy;
6. Uphold the law and justice in an orderly manner, proportionally, and democratically.

#### **B. Completion to the Results of Handling**

1. The report on handling of public complaints should be followed by further action in line with the provisions of the current laws and regulations in effect, namely:
  - a. administrative action;
  - b. demand by the treasury and demand for indemnity;
  - c. civil lawsuit or claim; reporting criminal acts;
  - d. improving the management of the institution concerned.
2. For the Person Reporting  
The head of the institution, or the authorized official can deliver information regarding the results of investigating the public

complaint to the person reporting.

3. For the Person Reported
  - a. If the investigation results cannot be proven to be true and accurate, the Chairperson of the Indonesian Food and Drug Authority must immediately restore the reputation of the person who was reported;
  - b. If the investigation results contain the truth, the Chairperson of the Indonesian Food and Drug Authority must immediately take action pursuant to the current laws and regulations.
4. For the results of investigation
  - a. If the person reporting is not satisfied with the results of investigation and submits a complaint once more together with adequate supporting evidence, the Chairperson of the Indonesian Food and Drug Authority shall have to make a second review of the investigation results;
  - b. When the investigation results are considered inadequate or are not in accordance with the actual conditions and facts, APIP may conduct verification on the correctness of the investigation results.

### **C. Monitoring the Handling of Public Complaints**

Monitoring the results of handling public complaints shall be done by APIP.

1. Monitoring
  - a. Directly:
    - 1) Updating the data;
    - 2) Coordination meetings;
    - 3) Monitoring the institution that handles the case.
  - b. Indirectly:
    - 1) Through electronic communication;
    - 2) Through correspondence.
2. Proof of Handling

Proof of handling is the report on investigation results with supporting evidence attached.
3. Status of Handling

- a. In Process  
When the problem reported is still in the process of being handled by the Indonesian Food and Drug Authority.
- b. Completed
  - 1) APIP resolved the complaint with valid evidence and can account for the case; or
  - 2) APIP was unable to investigate the truth of the complaint because:
    - a) it had been delegated to, or handled by law enforcement officials; or
    - b) it is not under the authority of the Indonesian Food and Drug Authority; or
    - c) based on technical considerations regarding control, it was considered no longer possible to conduct an investigation or take follow-up action on this public complaint.

## **CHAPTER VI**

### **SANCTIONS**

1. The Head of a Work Unit that refuses to be investigated by APIP and/or does not follow the recommendations of the public complaint investigation report as he should, and/or protects the apparatus that violated the rules will be subject to an administrative sanction and/or other sanctions, in accordance with the provisions of the current laws and regulations in effect.
2. The Chairperson of the Indonesian Food and Drug Authority or the government apparatus responsible for handling public complaints that does not handle a public complaint within a period of 90 (ninety) days after the complaint letter is received without a reason that can be accounted for, will be subject to administrative sanction and or other sanctions in compliance with the laws and regulations in effect.
3. The Chairperson of the Indonesian Food and Drug Authority may impose administrative sanction and or other sanctions in accordance with the laws and regulations in effect, on the government apparatus that handles public complaints if it deviates from the ethics and standards when handling the public complaints.

4. The Chairperson of the Indonesian Food and Drug Authority may impose administrative sanction and or other sanctions in accordance with the laws and regulations in effect, on APIP if it was inaccurate in preparing the report on results of investigating the public complaint.

## **CHAPTER VII**

### **CLOSING**

The Procedures for Handling Public Complaints within the scope of the Indonesian Food and Drug Authority will be used as operational reference for the implementation of activities in the handling of public complaints received by the Indonesian Food and Drug Authority and hopefully they will be able to increase the intensity and quality of the public services provided by the Indonesian Food and Drug Authority. Further, the follow-up to findings and results of the complaints can be used as input for considerations and serve as an *early warning system* for the management with regard to Food and Drug Authority, so as to improve the quality of public service by the Indonesian Food and Drug Authority.

CHAIRPERSON OF THE INDONESIAN FOOD AND  
DRUG AUTHORITY,

signed

PENNY K. LUKITO

## **SUB-ATTACHMENT I.1:**

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY  
NUMBER 27 YEAR 2018  
REGARDING  
PUBLIC SERVICE STANDARDS WITHIN THE SCOPE OF  
THE INDONESIAN FOOD AND DRUG AUTHORITY

**SERVICE STANDARD OF THE  
APPLICATION FOR DRUG REGISTRATION**

**PART ONE  
INTRODUCTION**

**A. Legal Basis**

1. Law Number 36 Year 2009 on Health;
2. Government Regulation Number 72 Year 1998 on The Safety of Pharmaceutical Preparations;
3. Government Regulation Number 32 Year 2017 on Types and Rate on Types of Non-Tax State Revenue at the Indonesian Food and Drug Authority;
4. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.00.05.3.1818 Year 2005 on Guide for Bioequivalence Testing;
5. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.00.05.1.3682 Year 2005 on Procedures of Bioequivalence Testing;
6. Regulation of the Health Minister Number 1010/MenKes/PER/XI/2008 on Registration of Drugs as amended by the Regulation of the Health Minister Number 1120/MenKes/PER/XII/2008;
7. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.23.12.11.10217 Year 2011 on Drugs Required to Undergo Equivalence Testing;
8. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 16 Year 2015 on Management and Assessment of Newly Developed Drugs;
9. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 21 Year 2015 on Approval of Clinical Trials;

10. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 24 Year 2017 on the Criteria and Procedure of Drug Registration.

## **B. Purpose and Objective**

**The purpose of determining service standards** is to provide reference for the applicant in submitting a request for the registration of drugs and clinical trials, and to serve as guidelines for providing registration of drugs and clinical trials.

**The objective of service standards** is to:

- a. Increase the applicant's understanding of the procedure and requirements for registration of drugs and clinical trials in line with the provisions of the laws and regulations in effect.
- b. Provide service for the registration of Drugs and Biological Products, publishing the Approval to Conduct Clinical trials and Approval on the Protocol for Bioequivalence Trials that are timely and in accordance with the criteria of safety, efficacy and quality.

## **C. Definition/General Meaning**

1. **Approvable Letter** (Notice of Approval) is a written notice of approval to make preparations for manufacturing drugs on a commercial scale or preparations for importing drugs before an approval is issued for a Marketing Permit.
2. **Marketing Permit** is a form of approval for the registration of drugs so that they can be marketed in the territory of Indonesia.
3. **Drug** is a manufactured medicine, including biological products, which is an ingredient or mixture of ingredients used to influence or to investigate the physiological system or pathological conditions in order to determine a diagnosis, or prevention, healing, recovery, improvement of health, and contraception for humans.
4. **New Drug** is a drug containing a new active substance, new form of preparation, new strength or new combination that had never been approved before in Indonesia.
5. **Generic Drug** is a drug with the name as provided in the *International Nonproprietary Names Modified* determined by the World Health Organization (WHO) or a name determined in the national health program.

6. **Branded Generic Drug** is a drug using a trade name that contains an active substance with the composition, strength, form of preparation, route of administering, indications and dosage which is the same as the originator drug already approved in Indonesia.
7. **New Developed Drug**, or abbreviated as **NDD**, is a drug or drug ingredient which is a new molecule, biological/biotechnological product that is being developed and manufactured by a research institution or pharmaceutical company in Indonesia and/or outside of Indonesia to be used in the non-clinical testing stage and/or clinical tests in Indonesia for the purpose of obtaining marketing authorization (marketing permit) in Indonesia.
8. **Pre-Registration** is a procedure in registration that intends to filter the registration of drugs, and determine the category of registration, determine the path of evaluation, determine the cost of evaluation, and determine the documents for drug registration.
9. **Biological Product** is a product that contains biological material from humans, animals or micro-organism and which is produced in conventional ways, among others through extraction, fractionating, reproduction, cultivation or through biotechnological methods such as fermentation, genetic modification, cloning, including but not limited to using enzymes, monoclonal antibodies, hormones, stem cell, gen therapy, vaccines, blood products, recombinant DNA products, and immunosera.
10. **Registration** is the procedure of registering and evaluating drugs in order to obtain a marketing permit.
11. **New Registration** is the registration of drugs that have not yet obtained a permit or authorization to be marketed in Indonesia.
12. **Re-Registration** is an extension of the registration for a marketing permit.
13. **VariationRegistration** is the registration of changes in the administrative aspects, efficacy, safety, quality, and/or Product Information and Medicine Labels that already have a Marketing Permit for Indonesia.
14. **Registration Variation Notice** is the variation registration that has minimum effect or no effect at all on the efficacy, safety, and/or quality of the drug and does not change information on the marketing permit document.

15. **Bioequivalence Testing** is the testing of bioavailability or comparative pharmacodynamics designed to indicate the bioequivalence between the test drug (copy drug) and the innovator/comparator drug.
  
16. **Clinical Testing** is any research done on humans with the intention of finding out or making sure of the clinical, pharmacological and/or pharmacodynamic effects of the product being investigated; and/or to identify any undesirable reactions towards the product being investigated, and/or to study the absorption, distribution, metabolism and excretion of the product investigated in order to ensure its safety and/or effectiveness.

**PART TWO**  
**FRAMEWORK AND STANDARD PROCEDURE OF SERVICES**

**Framework of Procedures**

| <b>No.</b> | <b>Type of Service</b>  | <b>Time of Completion</b>   | <b>Cost/Rate</b>  | <b>Service Product</b>  |
|------------|---|---|---|---|
| 1.         | Request for Pre-Registration of Drugs and Biological Products | 40 days   | According to PP Number 32 Year 2017 on Types and Rate on Types of PNBP Applied at BPOM (Indonesian Food and Drug Authority) | Pre-Registration Result (HPR)   |
| 2.         | Request for Registration of New Drugs and Biological Products | <ul style="list-style-type: none"> <li>•7 days</li> <li>•100 days</li> <li>•120 days</li> <li>•150 days</li> <li>•300 days</li> </ul> |   | <ul style="list-style-type: none"> <li>• Approvable Letter</li> <li>• Marketing Permit Number (NIE)</li> <li>• Approvable Letter for Export</li> <li>• Approvable Letter for Import of Bulk Products</li> <li>• Rejection Letter</li> </ul> |

| <b>No.</b> | <b>Type of Service</b>  | <b>Time of Completion</b>  | <b>Cost/Rate</b> | <b>Service Product</b>   |
|------------|---|--|------------------|--|
| 3.         | Request for Registration of Variation to Drugs and Biological Products          | <ul style="list-style-type: none"> <li>• Registration of Variation Notification*</li> <li>• 40 days</li> <li>• 100 days</li> <li>• 120 days</li> <li>• 300 days</li> </ul> |                  | <ul style="list-style-type: none"> <li>• Approvable Letter to Change</li> <li>• Approval to Notification</li> </ul>  |
| 4.         | Request for Re-Registration of Drugs and Biological Products (without change)** | <ul style="list-style-type: none"> <li>• 10 days***</li> </ul>   |                  | Marketing Permit Number (NIE)****  |
| 5.         | Request for Approval to Conduct Clinical Trial/Testing                          | <ul style="list-style-type: none"> <li>• 20 days</li> </ul>  |                  | <ul style="list-style-type: none"> <li>• Approvable Letter to Conduct Clinical Trial</li> <li>• Notice of Clinical Trial</li> <li>• Letter of Approval to Amend Clinical Trial Documents</li> <li>• Approval to Import Clinical Test Drugs</li> <li>• Request to Correct the Clinical Trial Documents</li> </ul> |
| <b>No.</b> | <b>Type of</b>  | <b>Time of</b>   | <b>Cost/Rate</b> | <b>Service</b>   |

|   | <b>Service</b>   | <b>Completion</b> |  | <b>Product</b>  |
|---|--|-------------------|--|---|
| 6 | Request for Approval on Protocol of Bioequivalence Testing | • 20days          |  | <ul style="list-style-type: none"> <li>• Letter of Approval for Protocol of Bioequivalence Testing BE (PPUB)</li> <li>• Letter of Approval for Changes in Protocol of BE Testing</li> <li>• Request for Corrections to BE Test Documents</li> </ul> |
| 7 | Request for OPB Assessment                                 | • 100days         |  | <ul style="list-style-type: none"> <li>• Result of Evaluation on OPB Process</li> <li>• Letter of Approval for Clinical Testing (PPUK)</li> </ul>   |

\* The registrant can make changes and report this to the Head of the Agency at the latest 6 months from the time of making the changes.

\*\* Not including medicinal products where there has been a change in the active substances, change in the manufacturer, change in the registrant, change in form of preparation, change in formula, change in type and size of packaging, and/or a violation occurred against the provisions of the laws.

\*\*\* Re-registration can be requested at the earliest 12 months and at the latest 2 months before the marketing permit expires.

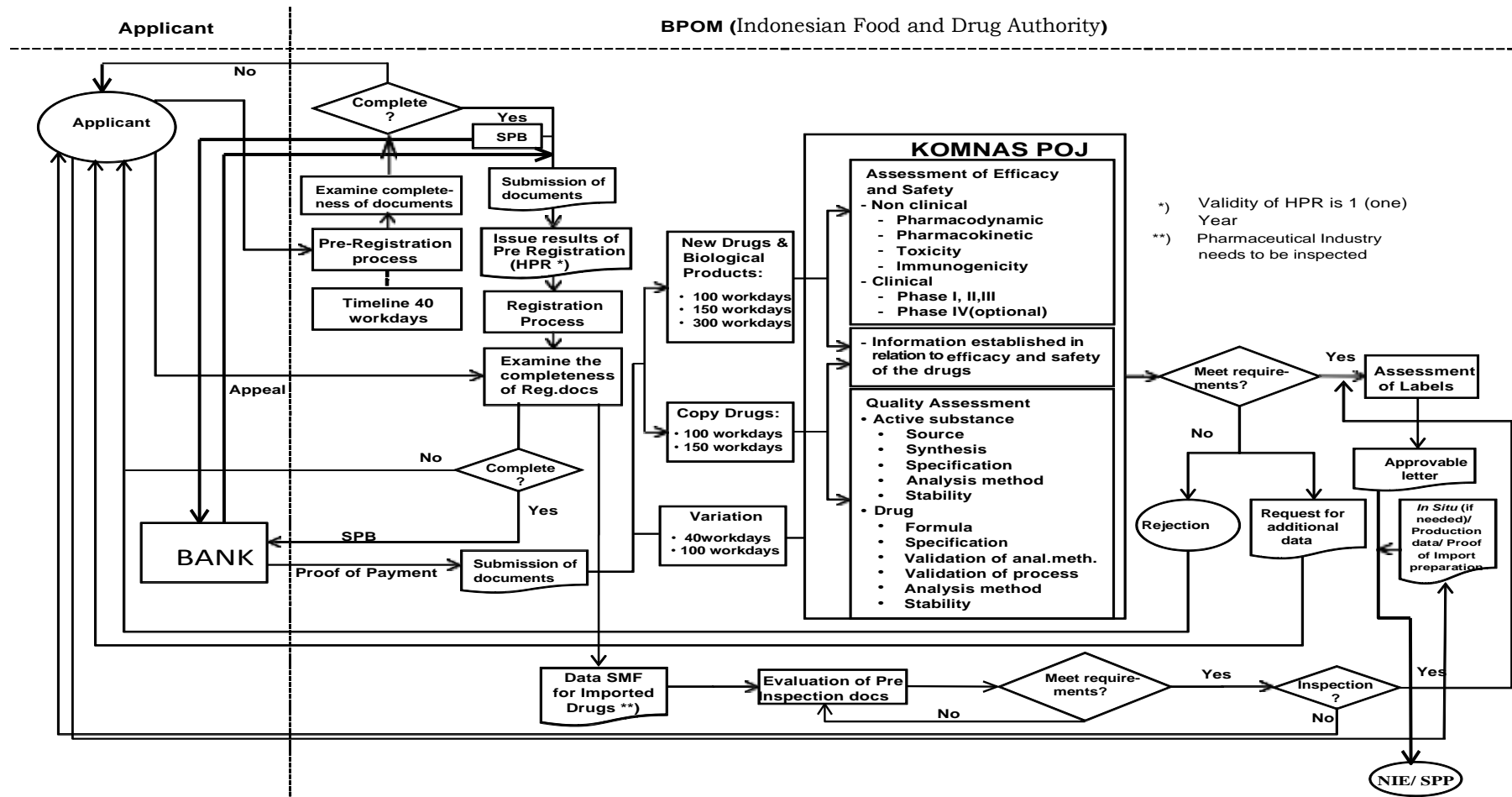
\*\*\*\* When there is new data related to the safety, efficacy and/or rationality of the formula, then extension of the approval on marketing permit should be reviewed again.

Note:

- a. The system of calculating time is *clock on* and *lock off*, where the timeline is calculated as of receiving the Registration Form and proof of payment to the bank;
- b. Should the result of further Assessment require additional data or a further review, then the timeline shall be temporarily stopped (*off*) as of the date after the receiving the letter of request for additional data; and
- c. The timeline that was temporarily stopped will be resumed after the date of receiving notice that the request for additional data has been fulfilled (*on*).

## B. Procedure of Services

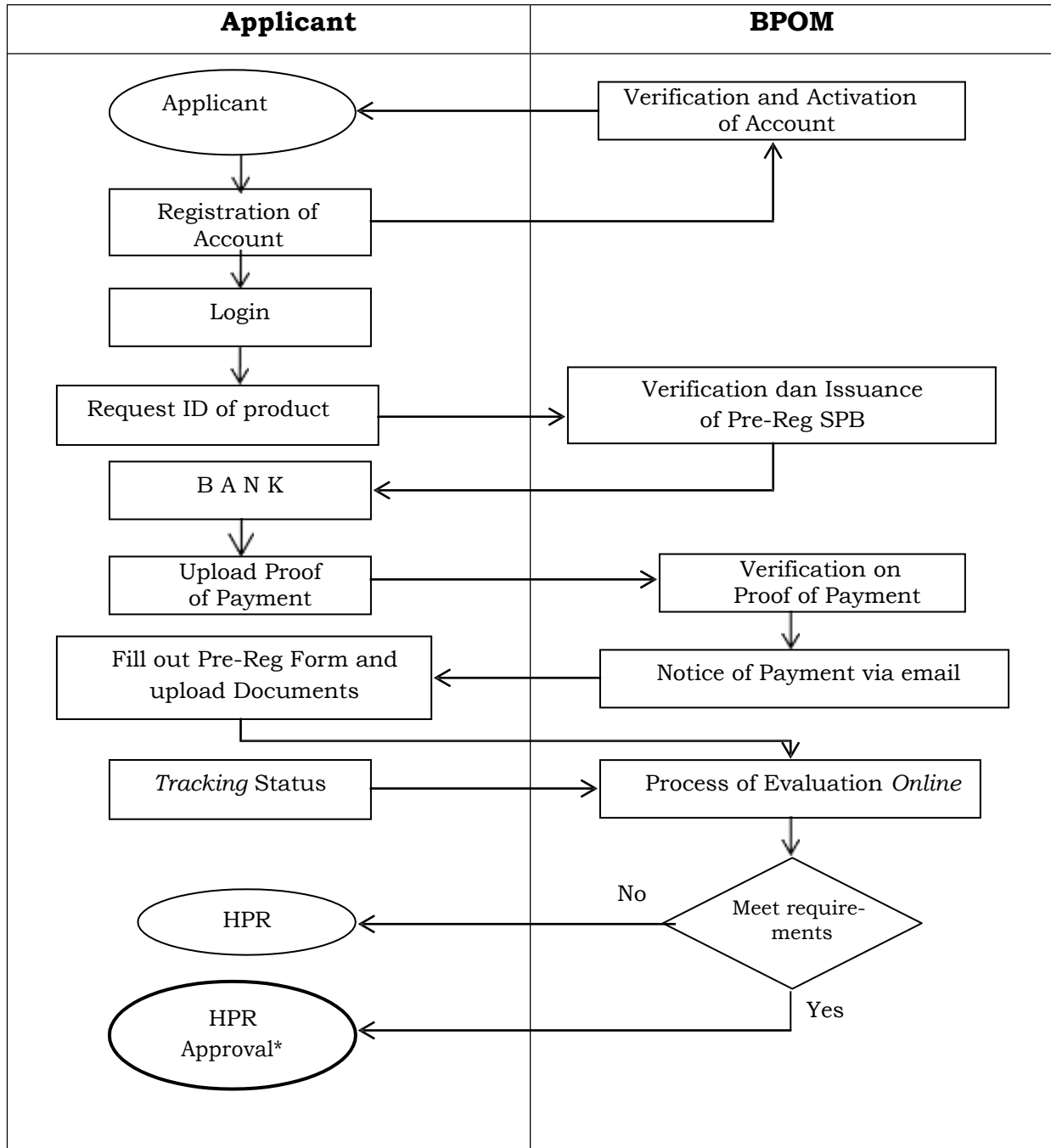
### 1. Request for Registration and Evaluation of Drugs and Biological Products



\* Request/application for pre-registration and registration can be submitted electronically.

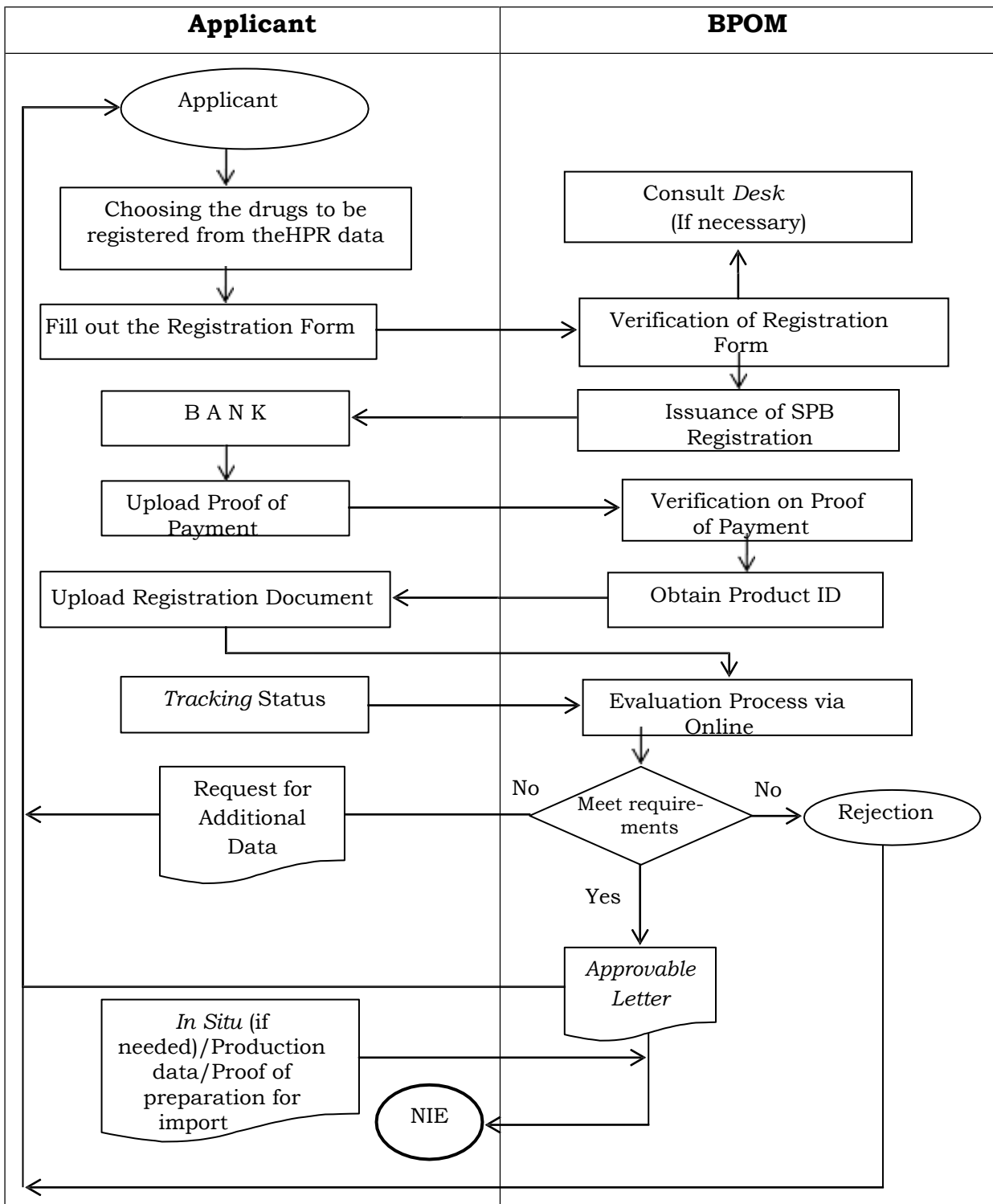
# 1. Application for Drug Registration (Electronically)

## a. Flow of Application for Drug Pre-Registration (Electronically)

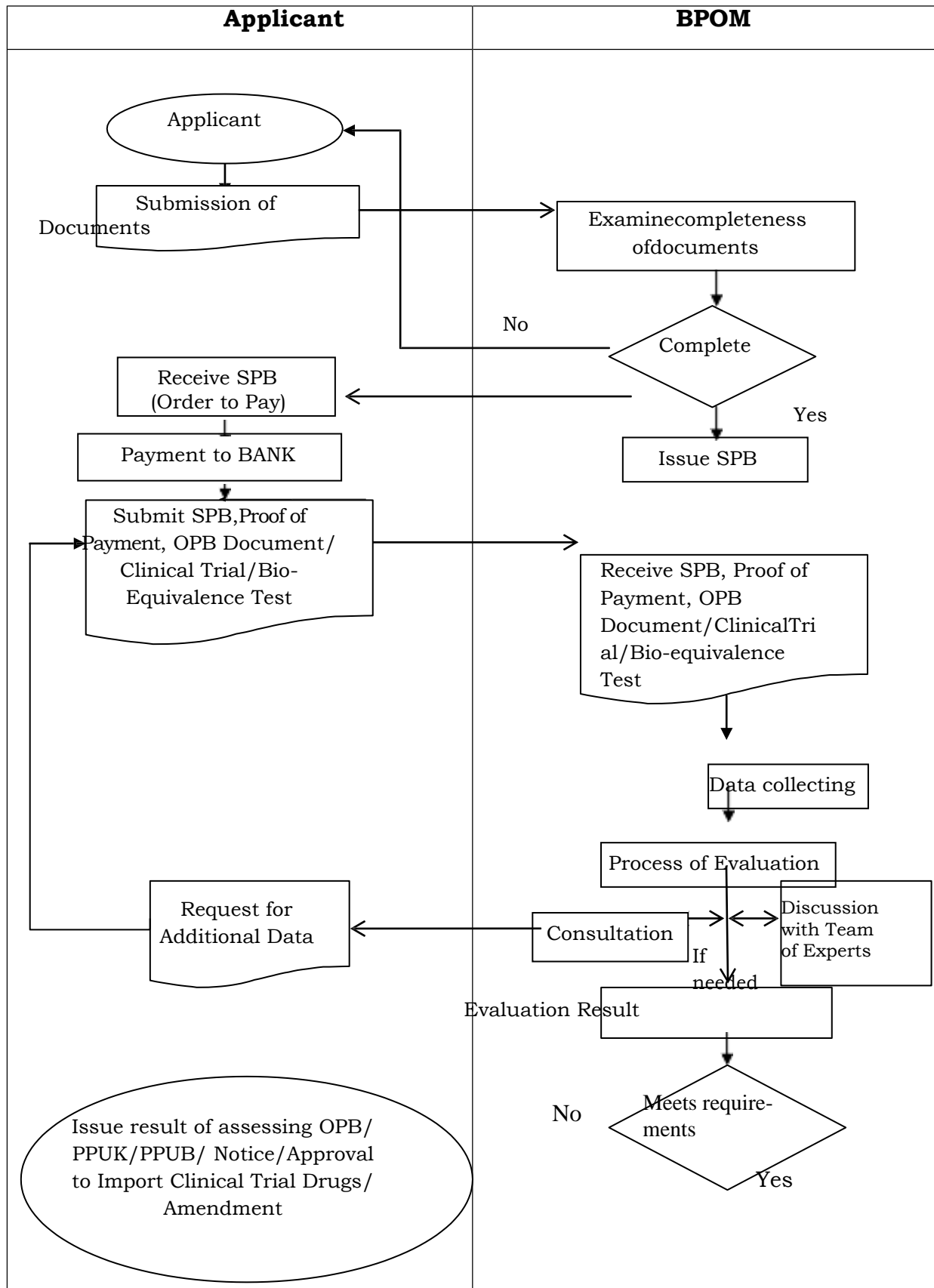


\* Validity of HPR (Result of Pre-Registration) is 1 (one) Year

**a. Flow of Application for Drug Registration (Electronically)**



## 2. Application for Assessment of OPB, Approval to Conduct Clinical Trial and Protocol for Bioequivalence Test



## **A. Schedule of Services**

### 1. Administration

Monday–Thursday : 08.30 –16.00WIB

Break : 12.00 – 13.00WIB

### 2. Receive Registration

Monday–Thursday : 08.30 –15.00WIB Break

: 12.00 – 13.00WIB

### 3. Consultation Services

Monday–Thursday : 09.00 –16.00WIB Break

:12.00 – 13.00WIB

Friday : 09.00 – 16.00WIB

Break : 11.30 – 13.30WIB

## **B. Service Facilities and Infrastructure**

1. Service Room;
2. Service Desk;
3. Computer;
4. Internet;
5. Charging Station;
6. Waiting Room;
7. Drinking Water;
8. Queue System;
9. Suggestion Box;
10. Lift;
11. Toilet;
12. Parking Lot; and
13. Nursing Room.

## **E. Requirements**

1. Request for registration of drugs and biological products.
  - a. Cover letter.
  - b. Registration Form.
  - c. Statement of the Registrant.
  - d. Certificate and other administrative documents:
    - 1) Drugs manufactured in Indonesia.
      - a) Pharmaceutical Industry License.
      - b) Valid GMP Certificate for the preparation being registered.
      - c) Valid GMP Certificate for producers of active substances.
      - d) Data regarding the latest inspection of GMP and related changes of at most the past two years, issued by the Indonesian Food and Drug Authority.
    - 2) Licensed Drugs
      - a) Pharmaceutical Industry License or a supporting document with sufficient evidence for the research body/institution as issuer of the license.
      - b) Pharmaceutical Company as receiver of the license.
      - c) Valid GMP Certificate of the pharmaceutical company receiving the license, for the type of preparation being registered.
      - d) License Agreement.
    - 3) Domestically manufactured contract drug.
      - a) License of the pharmaceutical company that is registering the drug or making the contract.
      - b) License of the pharmaceutical company as the Receiver of Contract.
      - c) Valid GMP Certificate of the pharmaceutical company that is registering the drug or making the contract.
      - d) Valid GMP Certificate of the pharmaceutical company that is receiving the contract, for the type of drug preparation being contracted.
      - e) GMP Certificate for producers of active substances.
      - f) Contract Agreement.
    - 4) Drugs for Export.
      - a) Pharmaceutical Company License.
      - b) GMP Certificate of the Registrant.

- c) GMP Certificate or other equivalent document from the manufacturer according to the type/form of the preparation being registered (for imported drugs and export).
- d) GMP Certificate for producers of active substances.

5) Imported Drugs.

- a) Pharmaceutical Industry License of the manufacturer and the Registrant.
  - b) Appointment letter of the pharmaceutical company or the foreign product owner except when the Registrant is an affiliation of the parent company.
  - c) Certificate of Pharmaceutical Product (CPP) or other equivalent document from the manufacturing country and/or country where the batch release certificate was issued (if necessary).
  - d) Valid GMP Certificate of the manufacturer for the form of preparation registered or other equivalent document (including GMP certificate of the producer of active substances for biological products).
  - e) Data on the latest inspection of GMP and related changes of at most two years issued by the local drug control authority and/or drug control authority of another country.
  - f) GMP Certificate of active substance producer.
  - g) Justification for import.
  - h) Proof of balanced export and import activities (if necessary).
  - i) Result of Pre-Registration.
  - j) Receipt/Proof of Payment.
  - k) Other documents.
- e. Technical Documents

The completeness of documents for registration of drugs and biological products refers to the Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 24 Year 2017 regarding Criteria and Procedure of Drug Registration.

## 2. Request for Approval to Conduct Clinical Trial

### a. Administrative Documents

- 1) Cover Letter
- 2) Order To Pay (SPB)
- 3) Proof of PNBP Payment according to provisions of the law
- 4) UK-1 Form

### b. Technical Documents

- 1) Protocol for Clinical Trial
- 2) Approval of the Ethics Committee and Attendance Sheet of the Ethics Committee
- 3) Approval after receiving explanation (Informed Consent)
- 4) Investigator's Brochure
- 5) Document on the quality of clinical trial drugs (Information on test product, CoA, GMP Certificate, summary of protocol for production and testing of 3 consecutive batches (for biological products), lot release (for vaccines)
- 6) CV of the Investigator and certificate of CUKB Training
- 7) Laboratory Accreditation
- 8) Laboratory used for clinical trials
- 9) Insurance certificate for clinical trials (if any)
- 10) Letter of Authorization/Letter of Appointment (if using *Contract Research Organization (CRO)*)
- 11) Package Insert for drugs of clinical trials (if using drugs that are already registered)
- 12) Proforma Invoice (if any)
- 13) Summary of previous clinical trials (if not included in the Investigator's Brochure)
- 14) Advertisement for subject recruitment (if any)

## 3. Request for Approval on Protocol of Bioequivalence Testing

### a. Administrative Documents

- 1) Cover Letter
- 2) Order to Pay (SPB)
- 3) Proof of PNBP Payment according to provisions of the law
- 4) UB-1Form (original)

### b. Technical Documents

- 1) Protocol for BE Test

- 2) Informed Consent Form
- 3) GMP Certificate
- 4) Drug Analysis Certificate
- 5) Active Substance Analysis Certificate from the producer of raw material
- 6) Certificate on Standard Analysis of primary and or secondary comparators
- 7) Formula
- 8) Information on *batch size* of drug to be BE tested
- 9) Information regarding comparator drug content
- 10) Result of Comparable Dissolution Test Results of BE Test Drug vs Comparator Drug in 3 pH media (1.2; 4.5;6.8)
- 11) Approval of Ethics Committee
- 12) Attendance Sheet of Ethics Committee
- 13) Accreditation Status or Recognition by BE Test Laboratory
- 14) Accreditation of Clinic Laboratory for Screening of Subjects
- 15) Photocopy of Approval to Import Drugs through special channel mechanism/*Special Access Scheme* (SAS), for imported comparator drugs
- 16) Photocopy of the packaging of comparator drugs (box)
- 17) Literature

#### 4. Request for Appraisal of New Developed Drugs

##### a. Administrative Document

- 1) Cover Letter
- 2) Order To Pay (SPB)
- 3) Proof of PNBP Payment according to provisions of the law
- 4) OPB-1 Form

##### b. Technical Documents

- 1) Summary of quality document (information on active substance, process of making an active substance, quality control, determining the content/potential active substance, formulation and how to manufacture drugs, stability).
- 2) General information on products, (source of raw material/antigen (active substance), nomenclature, chemical formula, summary of product characterization).

- 3) Process of manufacturing and control
- 4) Characterization including validation for critical process
- 5) Total characterization of the lot/batch (OPB phase III)
- 6) Specification and method of testing the active substance, additional substance and intermediate products.
- 7) Specification and testing the packaging
- 8) Testing the stability
- 9) Non-clinical overview
- 10) Drug master file (if available)
- 11) Clinical floating program
- 12) Documents for the request to get approval to conduct clinical trial  
(see Part 2, Request for Approval to Conduct Clinical Trial)

**F. Place of Services**

Public Service Building

Indonesian Food and Drug Authority

Jl. Percetakan Negara No.23, Central Jakarta 10560

## **SUB-ATTACHMENT I.2:**

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY  
NUMBER 27 YEAR 2018  
REGARDING  
PUBLIC SERVICE STANDARDS WITHIN THE SCOPE OF  
THE INDONESIAN FOOD AND DRUG AUTHORITY

**SERVICE STANDARDS OF THE  
APPLICATION FOR QUASI-DRUG REGISTRATION**

**PART ONE  
INTRODUCTION**

### **A. Legal Basis**

1. Law Number 36 Year 2009 on Health;
2. Government Regulation Number 72 Year 1998 on Safety of Pharmaceutical Preparations;
3. Government Regulation Number 32 Year 2017 on The Types and Rate on Types of Non-Tax State Revenue at the Indonesian Food and Drug Authority;
4. Regulation of the Minister of Health Number 006 Year 2012 on The Industry and Business of Traditional Medicines;
5. Regulation of the Minister of Health Number 007 Year 2012 on Registration of Traditional Medicines;
6. Regulation of the Head of the Indonesian Food and Drug Authority Number HK.00.05.41.1384 Year 2005 regarding Criteria and Procedure for Registration of Traditional Medicines, Standardized Herbal Medicines, and Phytopharmaca;
7. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.23.06.10.5166 Year 2010 on Providing Information on the Source of Certain Ingredients, Alcohol Content, and Date of Expiry on the Label of Medicines, Traditional Medicines, Food Supplements, and Food Products;
8. Decision of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.23.06.11.5629 Year 2011 on Technical Requirements for the Good Manufacturing of Traditional Medicines;

9. Decision of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.33.12.12.8195 Year 2012 on Applying the Guidelines for Good Manufacturing Practice of Medicines;

## **B. Purpose and Objectives**

**The purpose of determining service standards** is to provide reference for the applicant who submits a request for registration of quasi-drugs and to become the guidelines for providing service related to the registration of quasi-drugs.

**The objective of service standards** is to:

- a. Increase the applicant's understanding about how to register quasi-drugs in compliance with the provisions of the laws and regulations in effect.
- b. Provide timely performance in the registration of quasi-drugs in accordance with the criteria for safety, efficacy/benefits and quality.

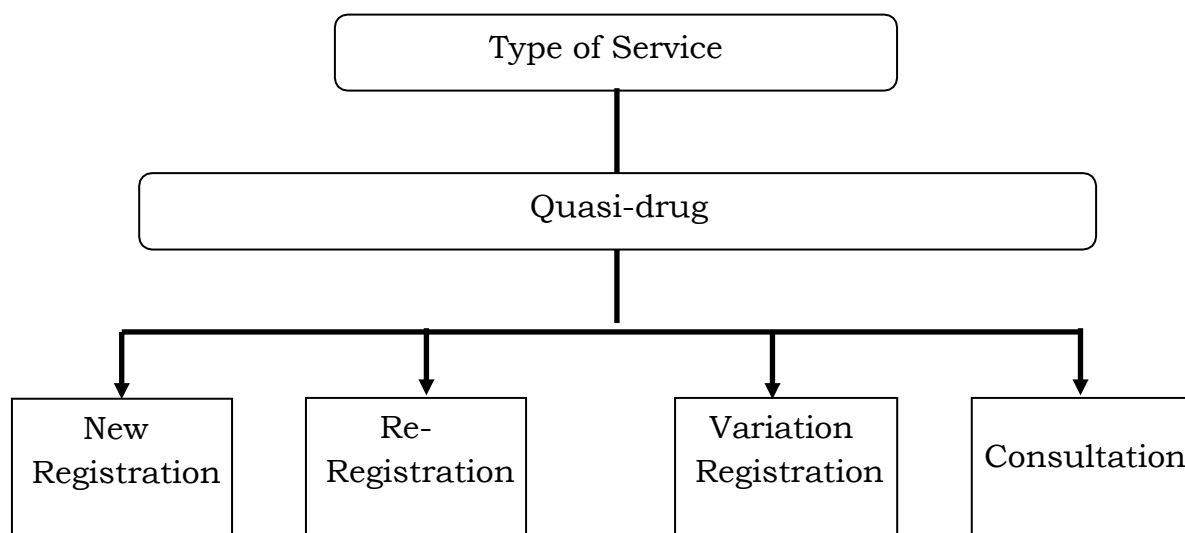
## **C. Definition/General Meaning**

1. **Marketing Permit** is an approval on the registration of quasi-drugs given by the Chairperson of the Authority so that the drug can be marketed in Indonesia.
2. **Quasi-drug** is a preparation containing active ingredients that have a pharmacological effect to overcome minor ailments.
3. **Good Manufacturing Practice**, that can be abbreviated as **GMP**, is a method of manufacturing drugs with the intention to assure that the quality of the drug produced is in accordance with the requirements and objective of its use.
4. **Good Manufacturing Practice for Traditional Medicines**, that can be abbreviated as **GMP-TM**, is all the aspects of manufacturing traditional medicine with the intention to assure that the product produced shall consistently meet the fixed requirements for quality and is in accordance with the objective of its use.
5. **Labeling** is the complete information about the efficacy, safety, instructions for use and other information considered necessary to be included on the label and/or brochure that accompanies the quasi-drug and on the packaging.
6. **Registrant** is the customer/applicant.

7. **Pre-registration** is a procedure in registration that examines the completeness and validity of documents as a filter before registration of the quasi-drug, to determine the category of registration, the path of evaluation, and the cost of evaluation.
8. **Registration** is the process of registering and evaluating the quasi-drug in order to obtain a marketing permit.
9. **Re-Registration** is registration to extend the term of validity of the marketing permit.
10. **Expert Team** is a committee consisting of experts in certain fields, formed by the Indonesian Food and Drug Authority (BPOM) whose task is to assist certain technical units of BPOM in making decisions when evaluating the registration of a product.
11. **Variation** means a change in the administrative data and/or technical data of the quasi-drug that had already obtained a marketing permit.

**PART TWO**  
**FRAMEWORK AND STANDARD PROCEDURE**  
**OF SERVICES**

**A. Type of Service**



**B. Framework of Procedures**

| <b>No.</b> | <b>Type of Service</b>                     | <b>Time of Completion</b>  | <b>Cost/Rate</b>  | <b>Service Product</b>   |
|------------|--|--|---|--|
| 1          | Request for Pre-Registration of Quasi-drug | 15 days  | According to PP (Gov.Reg.)<br>Number 32   | Pre-registration Result (HPR)  |
| 2          | Request for New Registration of Quasi Drug | <ul style="list-style-type: none"> <li>• 30days</li> <li>• 60days</li> </ul> | Year 2017 on Types and Rate on Types of PNBPN (Non-Tax State Revenue)<br>Applicable at BPOM | <ul style="list-style-type: none"> <li>• Marketing Permit Number (NIE)</li> <li>• Letter of Rejection</li> </ul> |

| No. | Type of Service                                   | Time of Completion   | Cost/Rate | Service Product  |
|-----|---|--|-----------|--|
| 3   | Request for Registration of Quasi-drug Variation  | <ul style="list-style-type: none"> <li>• 5 days</li> <li>• 7 days</li> <li>• 30days</li> </ul> |           | <ul style="list-style-type: none"> <li>• Marketing Permit (NIE)</li> <li>• Approvable Letter</li> <li>• Letter of Rejection</li> </ul> |
| 4   | Request for Re-Registration (without any change*) | 10 days  |           | <ul style="list-style-type: none"> <li>• Marketing Permit Number (NIE)**</li> </ul>  |
| 5   | Request for Registration for Export               | 3 days   |           | <ul style="list-style-type: none"> <li>• Marketing Permit Number (NIE)</li> <li>• Approvable Letter</li> </ul>                         |

\* Submission of the request for re-registration should be done at the earliest 90 (ninety) calendar days and at latest 1 (one) calendar day before expiry of the marketing permit.

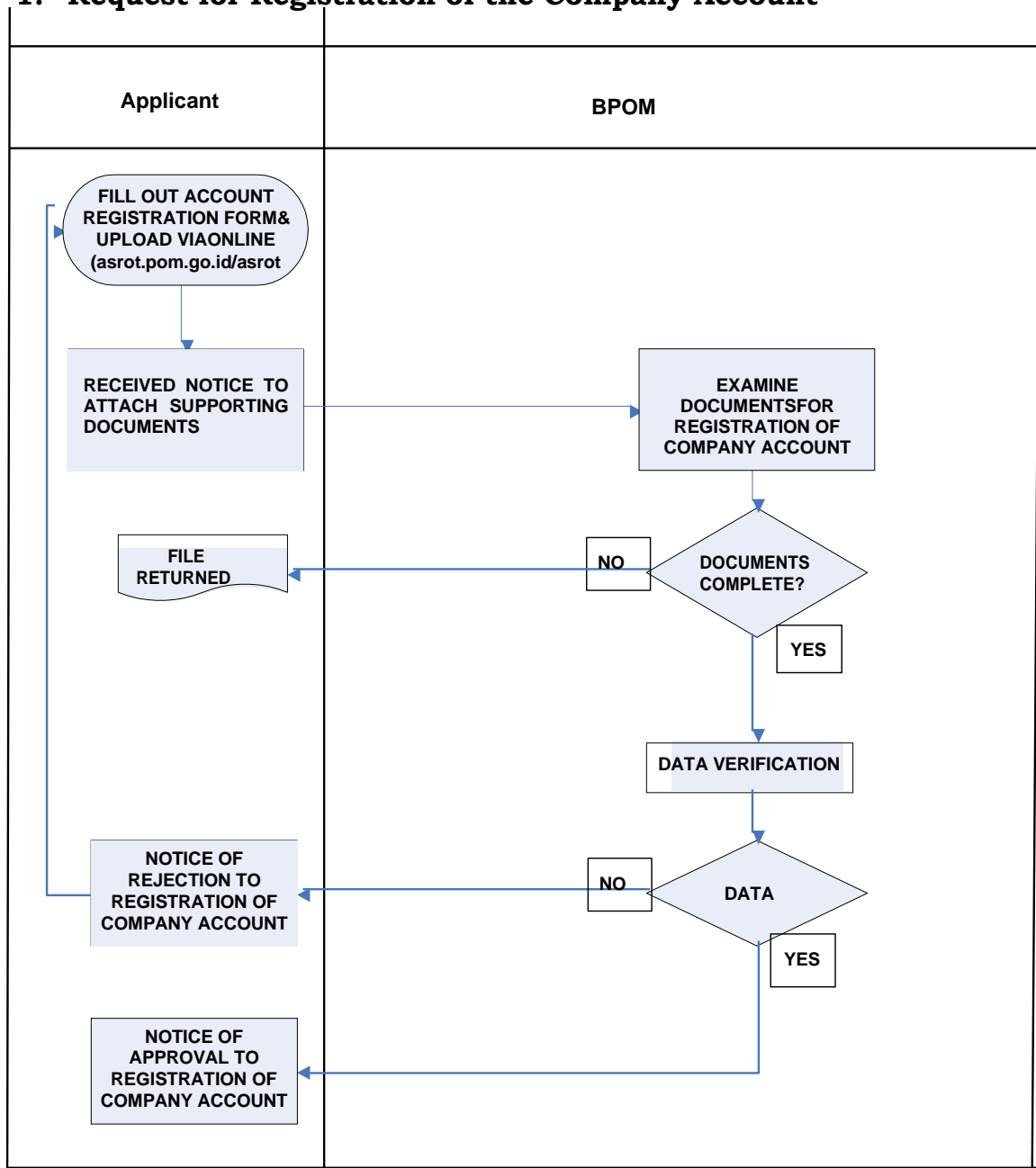
\*\* Should there be any new data related to the safety, efficacy and/or rationality of the formula, then the extension of approval for a marketing permit shall be reviewed again.

Note:

- a. The system of calculating time is *clock on* and *clock off*, where the timeline is calculated as of receiving the proof of payment to the bank;
- b. Should the result of further Assessment require additional data or a further review, then the timeline shall be temporarily stopped (*off*) as of the date after the receiving the letter of request for additional data; and
- c. The timeline that was temporarily stopped will be resumed after the date of receiving notice that the request for additional data has been fulfilled (*on*).

## C. Service Procedure

### 1. Request for Registration of the Company Account



#### \* Supporting Documents:

##### a. Local

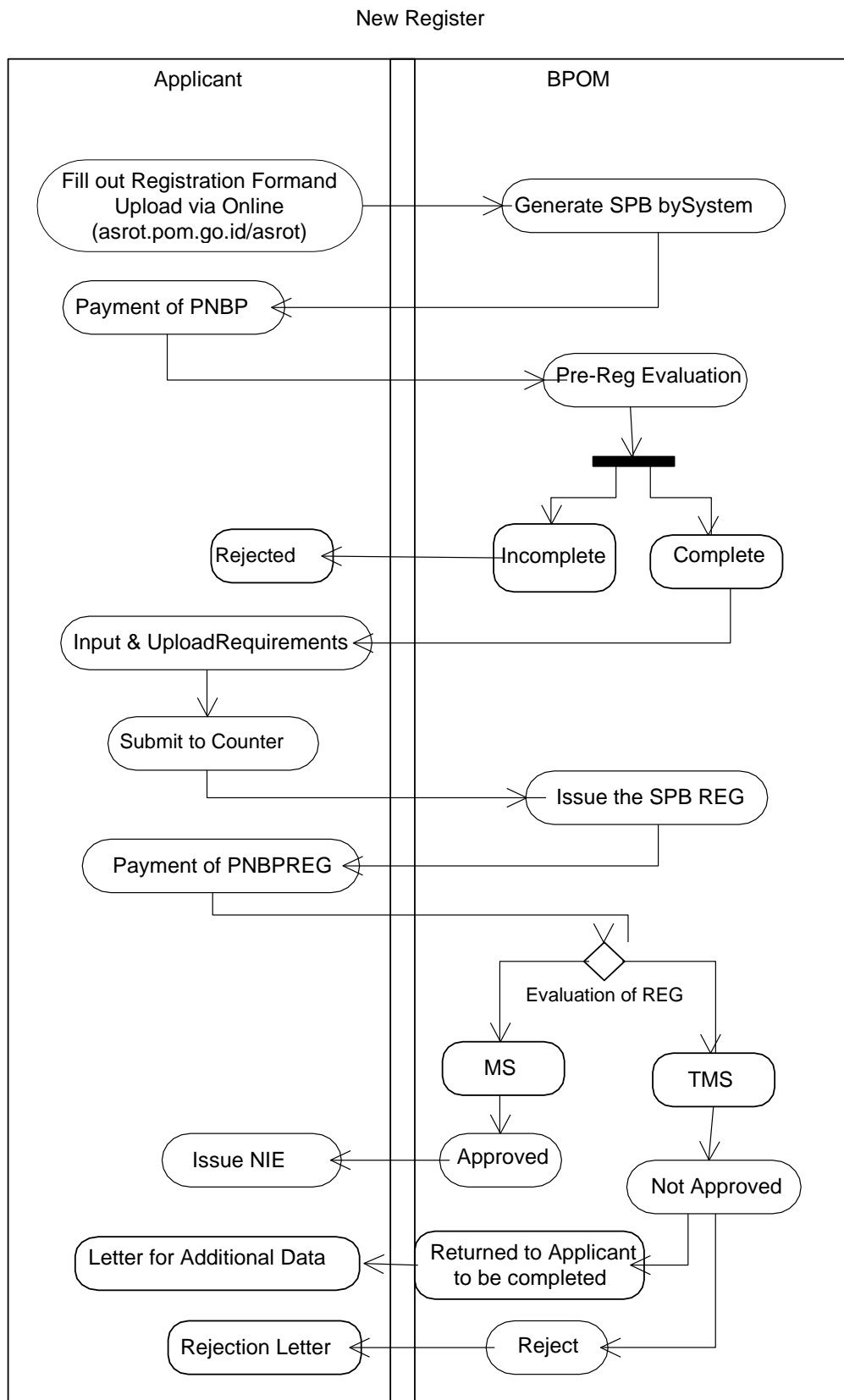
The GMP/GMP-TM certificate, recommendation to apply Good Manufacturing Practices, letter of approval to use joint facilities for the pharmaceutical industry.

##### b. Import

Recommendation on the results of examining the distribution facilities from the Directorate of Control on Traditional Medicines and Health Supplements or the Indonesian Food and Drug Authority /Center, *Good Manufacturing Practices (GMP) Certificate*, and the *Certificate of Free Sale (CFS)/Certificate of Pharmaceutical*

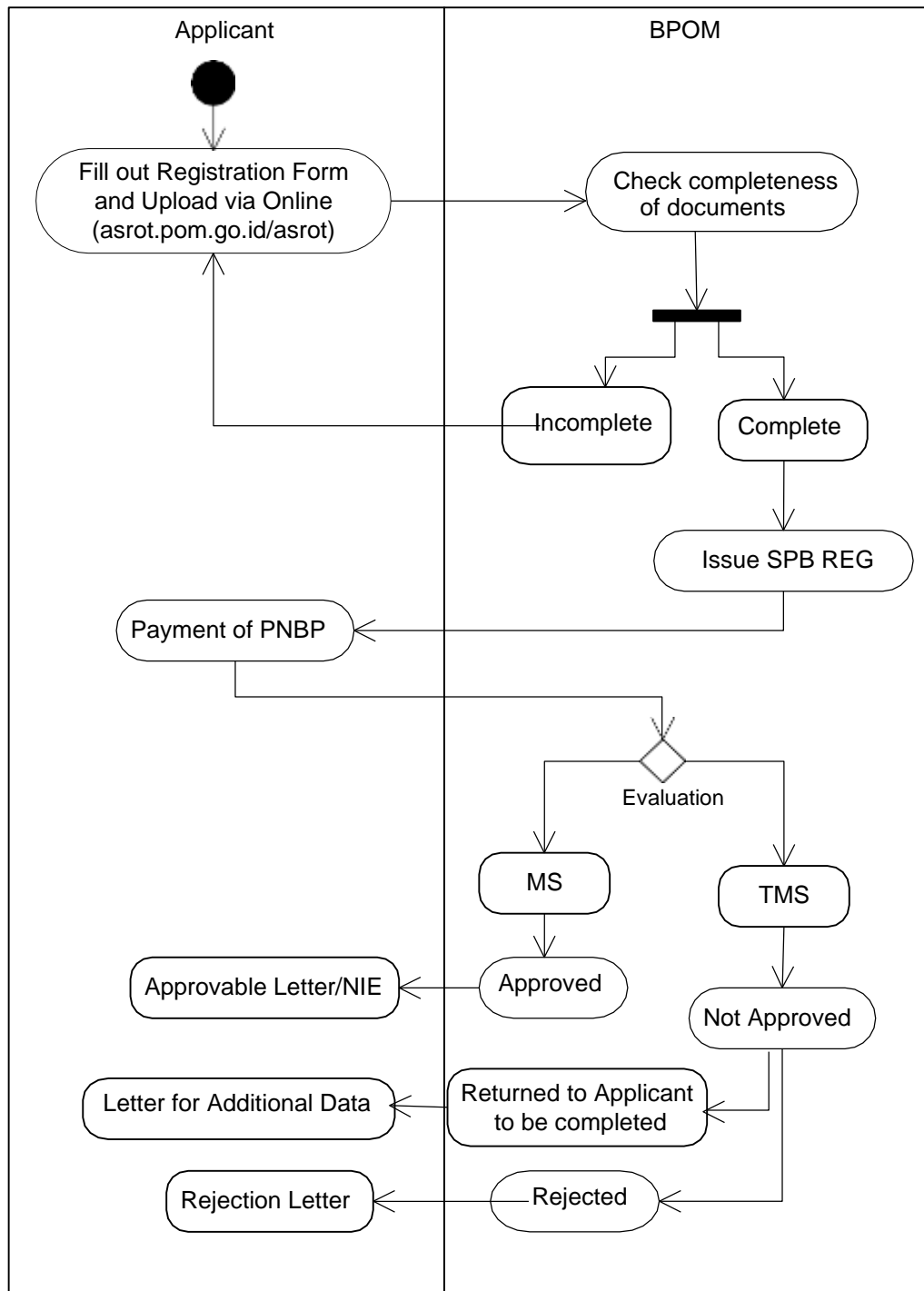
Product (CPP) if the form of preparation is not mentioned in the GMP Certificate.

## 2. Request for New Registration of Quasi-drug



### 3. Request for Registration of Variation or Re-registration of Quasi-drug

#### Re-Registration & Variation



#### **D. Schedule of Services**

a. Correspondence Counter

Monday – Thursday : 08.30 – 16.00 WIB

Break : 12.00 –13.00WIB

Friday : 08.30 –15.30WIB

Break : 12.00 – 13.30WIB

b. Counter Receiving Registration Files

Monday – Thursday : 08.30 – 16.00 WIB, without Break

c. Consultation between *DutyManagers*

Monday– Thursday :09.00 – 16.00 WIB Break

: 12.00 – 13.00WIB

d. IT Consultation Counter

Monday–Wednesday : 09.00 – 16.00 WIB

Break : 12.00 – 13.00WIB

#### **E. Service Facilities and Infrastructure**

a. Service Room;

b. Service Desk;

c. Computer;

d. Internet;

e. Waiting Room;

f. Suggestion Box;

g. Tools for Customer Satisfaction Survey

h. Drinking Water;

i. Charging station;

j. Queue system;

k. Lift;

l. Toilet;

m. Parking lot

n. Nursing room.

## **F. Requirements**

### 1. Request for New Registration

#### a. Administrative Documents

- 1) Registration Form containing the identity of the product and the manufacturer/company;
- 2) Registration of domestic quasi-drugs
  - Approval to use joint facilities;
  - Letter of agreement for cooperative contract / *toll manufacturing* for products that are made by contract;
  - Distribution agreement for products that mention the distributor on the label.
- 3) Registration of imported quasi-drugs and license
  - Letter of appointment of the agent/cooperative agreement for license of the industry in the country of origin that states the term of appointment, name, type of packaging, and composition of the product;
  - *Certificate of Free Sale (CFS)* or *Certificate of Pharmaceutical Products (CPP)* issued by the authorized government agency in the country of origin and legitimized by an official of the local Representative Office of the Government of Indonesia;
  - *Certificate of Good Manufacturing Practices (GMP)* issued by the authorized government agency in the country of origin or by a third party that was officially appointed by the local government;
  - *Certificate of GMP/GMP-TM / Recommendation to comply with GMP-TM* for the receiver of the license;
  - Letter of agreement for distribution of the products that state the name of the distributor on the label.

#### b. Technical Documents

##### 1) Formula and Method of Manufacturing

- Complete formula with active substances and additives per type of preparation in metric units;
- The amount of each ingredient used for 1 time manufacture (1 batch);
- Detailed method of manufacturing.

2) Examination of the Quality of Raw Material and Finished Product.

Quality of Raw Material

- *Certificate of Analysis* (CoA) and specification of raw materials from the producers of raw material;
- Identification of *simplicia* / extract such as the result of *achromatogram*, if needed.

Quality of Finished Product

- *Certificate of Analysis* (CoA) of the finished product contains the specifications, method of analysis, and results of testing;
- Protocol and result of longterm stability testing (*long term study*) at temperature of  $30 \pm 2^{\circ}\text{C}$  and relative humidity (RH)  $75 \pm 5\%$  in the form of a control table with time intervals of 0, 3, 6, 12, 18, 24 months and per year until expiry. Or the result of longterm stability testing (*long term study*) of at least 6 months along with the result of accelerated stability testing (*accelerated study*) with time intervals of 0, 3, 6 months, temperature  $40 \pm 2^{\circ}\text{C}$  and humidity of  $75 \pm 5\%$  and commitment for stability. Stability testing should be done at least one pilot scale for as many as 2 batches;
- Data on stability from the packaging factory if the product is packaged (*repacking*) in Indonesia.

Quality and safety testing includes:

- Testing the physical and chemical characteristics;
- Testing the active substance content;
- Microbiological testing (ALT, AKK, *Escherichia coli*, *Staphylococcus aureus*, *Pseudomonas aeruginosa*, *Salmonella sp.*, *Shigella sp.*);
- The origin and process of obtaining certain materials according to the provisions in effect;

- 3) Claims regarding the efficacy / benefits, instructions for use and system of numbering the batches;
- 4) Samples with the original packaging for imported products;
- 5) Design for colored labelling. Providing special information such as the logo for "Halal" products, trademarks and others on the package design should be accompanied by supporting data as according to the provisions in effect.

## 2. Request for Re-Registration

- a. Letter of request for re-registration;
- b. Formula of the products;
- c. Newest colored design;
- d. Approvable Letter and all types of variation that have been approved and the latest packaging design that was approved;
- e. Statement letter with duty stamp informing that the re-registration requested is for re-registration without any changes;
- f. Statement letter that the product is still being marketed. Local products can be declared with the last batch number, while imported products must mention the last Import Certificate (SKI);
- g. Contract agreement/ license /distribution letter that is still valid for products under a contract/license/that states the name of the distributor on the labeling;
- h. Letter of appointment from the producer in the country of origin, for imported products.

## 3. Request for Variation Registration.

A request for the registration of Variation will include administrative supporting data and/or quality in accordance with the changes submitted and based on the laws in effect.

### **G. Place of Services**

Public Service Building

Indonesian Food and Drug Authority

Jl. Percetakan Negara No.23, Central Jakarta 10560

## **SUB-ATTACHMENT I.3**

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY  
NUMBER 27 YEAR 2018  
REGARDING  
PUBLIC SERVICE STANDARDS WITHIN THE SCOPE OF  
THE INDONESIAN FOOD AND DRUG AUTHORITY

**SERVICE STANDARDS FOR THE  
REQUEST FOR APPROVAL TO CONDUCT PRE-CLINICAL/  
CLINICAL TESTING OF TRADITIONAL MEDICINES, HEALTH  
SUPPLEMENTS, AND COSMETICS**

**PART ONE  
INTRODUCTION**

**A. Legal Basis**

1. Law Number 36 Year 2009 on Health;
2. Government Regulation Number 72 Year 1998 on the Safety of Pharmaceutical Preparations;
3. Government Regulation Number 32 Year 2017 on the Types and Rate on Types of Non-Tax State Revenue at the Indonesian Food and Drug Authority;
4. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.00.05.4.2411 Year 2004 on Basic Rules of Grouping and Labelling Drugs with Natural Ingredients;
5. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.00.05.41.1381 Year 2005 on Procedure for Registration of Health Supplements;
6. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.00.05.41.1384 Year 2005 on the Criteria and Procedure for Registration of Traditional Medicines, Standardized Herbal Medicine and Phytopharmaca;
7. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.00.05.23.3644 Year 2005 on Basic Rules for Control of Food Supplements;
8. Regulation of the Minister of Health Number 1176/MENKES/PER/VIII/2010 Year 2010 on Notification of Cosmetics;

9. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.23.06.10.5166 Year 2010 on Providing Information Regarding the Origin of a Certain Ingredient, Alcohol Content, and Date of Expiry on the Label of a Drug, Traditional Medicine, Food Supplement, and Food Products;
10. Regulation Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.23.12.10.11983 Year 2010 on the Criteria and Procedure for Submitting Notification on Cosmetics;
11. Regulation of the Minister of Health Number 006 Year 2012 on the Industry and Business of Traditional Medicines;
12. Regulation of the Minister of Health Number 007 Year 2012 on the Registration of Traditional Medicines;
13. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 19 Year 2015 on Technical Requirements of Cosmetics;
14. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 21 Year 2015 on the Approval for Clinical Trials;
15. Decision of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.23.06.11.5629 Year 2011 on Technical Guidelines for Good Manufacturing Practice for Traditional Medicines;
16. Decision of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.33.12.12.8195 Year 2012 on Following the Guidelines for Good Manufacturing Practice;

## **B. Purpose and Objective**

**The purpose of determining service standards** is to provide reference for applicants in submitting a request for approval to conduct pre-clinical/clinical testing with traditional medicine, health supplements, and cosmetics.

**The objective of service standards** is to:

- a. Increase the applicant's understanding about requesting approval to conduct pre-clinical/clinical trials with traditional medicine, health supplements, and cosmetics which comply with the provisions of the current laws and regulations in effect.
- b. Provide service for the request to obtain approval for conducting pre-clinical/clinical trials with traditional medicine, health supplements,

and cosmetics that are timely and in accordance with the criteria of safety, efficacy/beneficial, and quality.

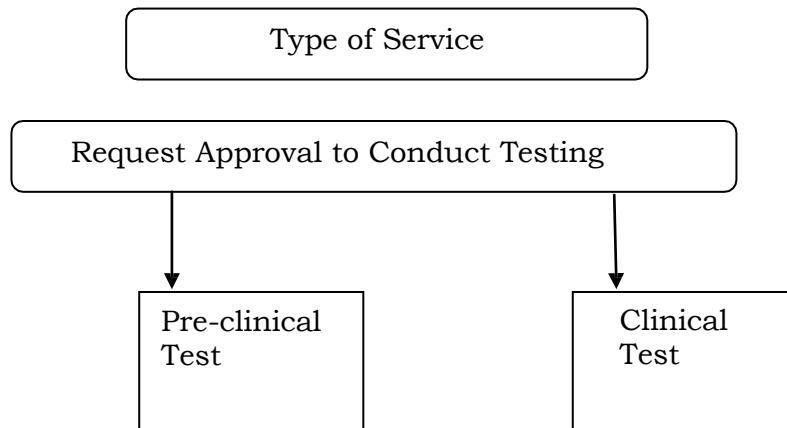
### **C. Definition/General Meaning**

1. **Good Manufacturing Practice for Traditional Medicine**, that will be referred to as **GMP-TM**, consists of all the aspects of manufacturing traditional medicine intended to guarantee that the product produced will always meet the requirements of good quality, pursuant to the objective of its use.
2. **Phytopharmaca** are medical preparations made from natural ingredients that have been proven safe and their efficacy has been proven scientifically through pre-clinical and clinical testing, both the raw materials and finished products have been standardized.
3. **Marketing Permit** is a form of approval for registration of traditional medicine, standardized herbal medicine, phytopharmaca, health supplements issued by the Chairperson of the Authority so they can be marketed in Indonesia.
4. **Jamu** is traditional Indonesian medicine.
5. **Cosmetics** are a material or preparation intended to be used on the outer part of the human body (epidermis, hair, nails, lips and outer genital organs) or the teeth and mucous membrane of the mouth particularly to clean, make fragrant, alter one's appearance and/or to eliminate body odour or to protect or keep the body in good condition.
6. **Standardized Herbal Medicine** is a medicinal preparation from natural ingredients and its safety and efficacy have been proven scientifically through pre-clinical tests, and the raw materials have been standardized.
7. **Traditional Medicine** is a substance or mixture of ingredients such as plants, animals, minerals, galenic preparations or a combination of such ingredients that have, from generation to generation, been used for medicinal purposes, and can be applied according to the norms of the community.
8. **Labeling** is complete information regarding the efficacy, safety, instructions for use and other information considered necessary and is printed on the label and/or brochure which is included with the traditional medicine, standardized herbal medicine and phytopharmaca, health supplement, as well as on the packaging.
9. **Registrant** is the customer/applicant.

10. **Health Supplement** is a product meant to fulfill the need for nutrients, to maintain, increase and/or improve the health function; it has nutritious value and/or physiological effect, contains one or more ingredients which can be vitamins, minerals, amino acids and/or non-plant ingredients that can be combined with plant ingredients.
11. **Expert Team** is a committee consisting of experts in their specific fields formed by the BPOM (Indonesian Food and Drug Authority) whose task is to assist BPOM's technical unit to make decisions related to the assessment of a product registration.
12. **Clinical Trial/Testing** is a research activity involving humans as the subject with intervention from a Test Product, to find out or confirm a clinical effect, pharmacological effect, and/or other pharmacodynamic effect, and/or to identify any unwanted reaction, and/or study the absorption, distribution, metabolism and excretion, for the purpose of ensuring the safety and/or effectiveness of the product being investigated.
13. **Day** is a work day.

**PART TWO**  
**FRAMEWORK AND STANDARD PROCEDURE**  
**OF SERVICES**

**A. Type of Service**



**B. Framework of Procedures**

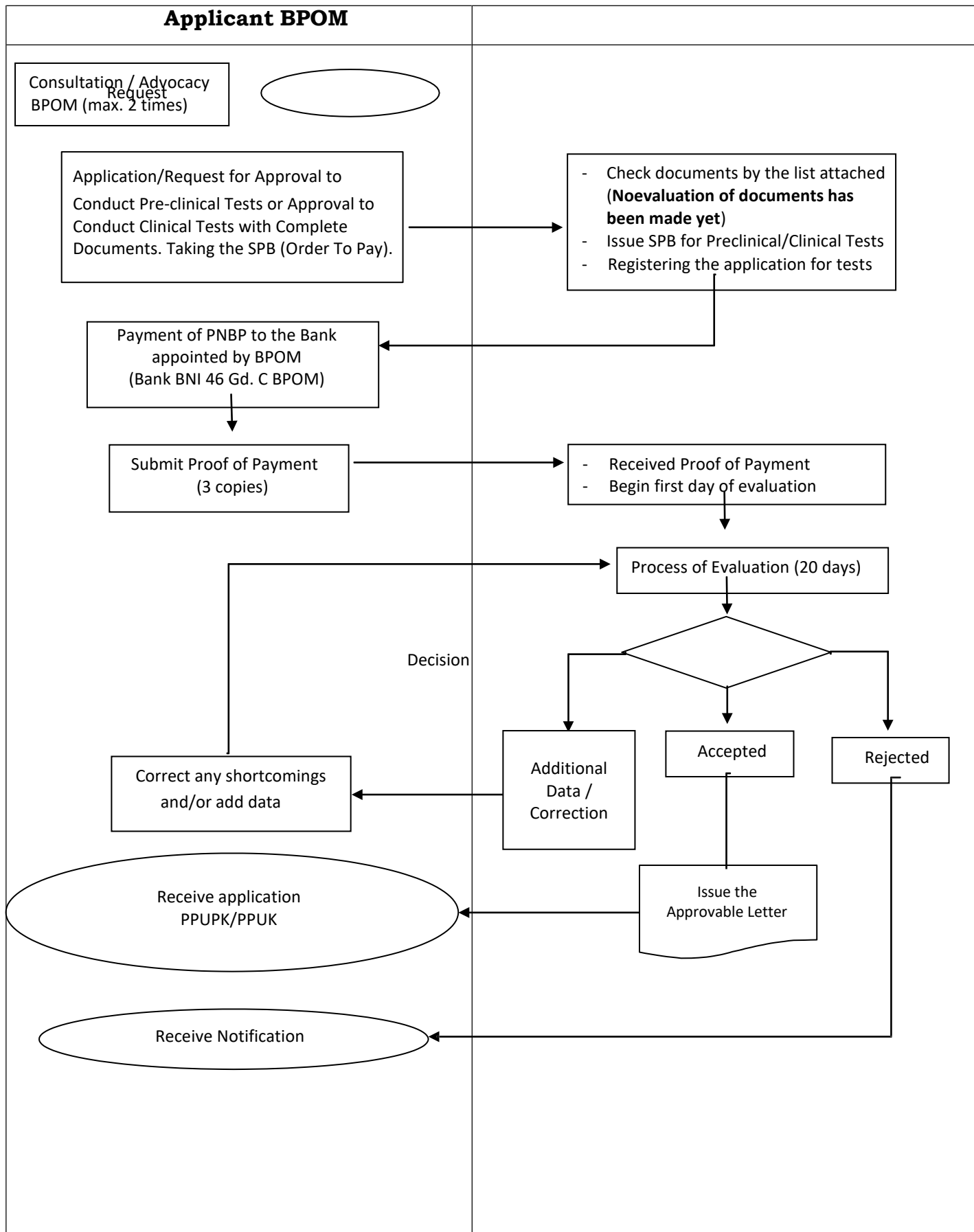
| <b>No.</b> | <b>Type of Service</b>                         | <b>Time of Completion</b> | <b>Cost/Rate</b>   | <b>Service Product</b>                                  |
|------------|--|---------------------------|--|---|
| 1          | Request approval to conduct pre-clinical tests | 20 days                   | According to PP Number 32 Year 2017 on Types and Rate on the Types of PNBP at BPOM | Approvable Letter to Conduct Pre-Clinical Tests (PPUPK) |
| 2          | Request approval to conduct clinical tests     | 20 days                   |  | Approvable Letter to Conduct Clinical Tests (PPUK)      |

Note:

Calculation of timeline begins as of the date the letter of request is received until the date that the letter of decision is issued.

### C. Procedure of Services

#### Request Approval to Conduct Pre-Clinical/Clinical Test



## **D. Requirements**

### **1. Request for Approval to Conduct Pre-clinical Test:**

#### a. Administrative Documents

- 1) Letter of Request for Approval to Conduct Pre-clinical Testing;
- 2) Order To Pay; and
- 3) Proof of payment of PNBP in accordance with the law.

#### b. Technical Documents

- 1) Protocol for pre-clinical testing;  
(acute toxicity test, sub-chronic/chronic toxicity test, pharmacodynamic test); Special toxicity (carcinogenic, teratogenic, etc.) if available;
- 2) Approval of the Ethics Commission;
- 3) Letter of Decision and design of the packaging that was approved, and any variation accompanying it (if the product is already registered);
- 4) Composition of the product;
- 5) Certificate of Analysis of the raw material;
- 6) Claims put forth;
- 7) Document on test product's quality; and
- 8) Composition of the research team.

### **2. Requirements of the Request for Approval to Conduct Clinical Testing/Trial:**

#### a. Administrative Documents

- 1) Letter of Request for approval to conduct clinical testing and import of the test product (if needed)
- 2) Order To Pay
- 3) Proof of payment of PNBP in accordance with the law
- 4) UK-1 Form

#### b. Technical Documents

- 1) Protocol for clinical test
- 2) Approval of Ethics Commission
- 3) Approval after explanation (*Informed consent*)
- 4) Investigator's Brochure/ information on the clinical test product
- 5) Document on quality of the test product (*CoA, GMP Certificate*)
- 6) CV of the Investigator and Certificate on having participated in CUKB training

- 7) Certificate of accreditation of the laboratory used for clinical test
- 8) Insurance Certificate for clinical test (if any))
- 9) Contract between the Sponsor and the contracted research organization (if using a research organization contract)
- 10) Data from the previous phase (non-clinical data, data of phase 1 or other scientific data according to need)
- 11) Composition of research team
- 12) Advertisement for *subject recruitment* (if any)

**E. Schedule of Services**

1. Counter for Receiving Files

Monday–Thursday : 08.30 –16.00WIB

Break : 12.00 – 13.00WIB

2. Consultation

Monday–Thursday : 09.00 –16.00WIB

Break : 12.00 – 13.00WIB

**F. Service Facilities and Infrastructure**

1. Service Room;
2. Service Desk;
3. Computer;
4. Internet;
5. Charging Station;
6. Waiting Room;
7. Drinking Water;
8. Queue System;
9. Suggestion Box;
10. Lift;
11. Toilet;
12. Parking Lot; and
13. Nursing Room

**G. Place of Services**

Public Service Building

Indonesian Food and Drug Authority

Jl. Percetakan Negara No.23, Central Jakarta 10560

## **SUB-ATTACHMENT I.4**

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY AND  
FOOD CONTROL  
NUMBER 27 YEAR 2018  
REGARDING  
PUBLIC SERVICE STANDARDS WITHIN THE SCOPE  
OF THE INDONESIAN FOOD AND DRUG AUTHORITY

**SERVICE STANDARDS OF THE  
APPLICATION FOR ASSESSMENT ON THE FULFILLMENT  
OF REQUIREMENTS NEEDED FOR GOOD MANUFACTURING  
PRACTICE (GMP) AT THE FACILITY FOR  
MANUFACTURE OF IMPORT DRUGS**

**PART ONE  
INTRODUCTION**

### **A. Legal Basis**

1. Strong Drugs Ordonance  
(*Sterkwerkende Geneesmiddelen Ordonnantie, Staatsblad 1949:419*);
2. Law Number 36 Year 2009 on Health;
3. Government Regulation Number 72 Year 1998 on The Safety of Pharmaceutical Preparations;
4. Government Regulation Number 32 Year 2017 on the Types and Rate on Types of Non-Tax State Revenue at the National Agency of Drug and Food Control;
5. Presidential Regulation Number 80 Year 2017 on National Agency of Drug and Food Control;
6. Regulation of the Minister of Health Number 1010/Menkes/Per/XI/2008 on Drug Registration as amended by the Regulation of the Minister of Health Number 1120/MENKES/PER/XII/2008 regarding Amendment to the Regulation of the Minister of Health Number 1010/Menkes/Per/XI/2008 on Drug Registration;
7. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.04.1.33.02.12.0883 Year 2012 on Master Document of the Pharmaceutical Industry and the Traditional

Medicine Industry;

8. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.33.12.12.8195 Year 2012 on Application of the Guidelines for Good Manufacturing Practice;
9. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 24 Year 2017 on Criteria and Procedure of Drug Registration;
10. Regulation of the Indonesian Food and Drug Authority Number 26 Year 2017 on the Organization and Working Procedures at the Indonesian Food and Drug Authority;
11. Regulation of the Indonesian Food and Drug Authority Number 29 Year 2017 on Control on Import of Drugs and Food into Indonesian Territory;
12. Regulation of the Indonesian Food and Drug Authority Number 30 Year 2017 regarding Control on Import of Drugs and Food into Indonesian Territory;.

## **B. Purpose and Objective**

**The purpose of determining service standards** is to provide guidelines for providing services as well as a reference for the stakeholders who wish to submit a request for assessment regarding fulfillment of the requirements for good manufacturing practice (GMP) of imported drugs, which includes assessment of the registration documents of the imported drugs, *desktop inspection*, inspection of the facilities used in manufacturing the import drugs, and evaluation of CAPA related to the result of inspecting the facilities for manufacturing import drugs, carried out in the framework of registering imported drugs.

**The objective of service standards** is to:

- a. Increase the understanding of the stakeholders in requesting assessment regarding the fulfillment of GMP facilities for manufacturing imported drugs.
- b. Establish a reference/guidelines for requesting assessment of the registration documents related to fulfilling GMP requirements, *desktop inspection*, inspection of the facilities for manufacturing import drugs, and evaluation of CAPA on the result of inspecting

the facilities for manufacturing imported drugs.

**C. Definition/General Meaning**

1. **Good Manufacturing Practice (GMP)**, which shall also be referred to as **GMP**, is a method of manufacturing drugs and/or material for drugs that intends to ensure the quality of the drugs and/or material produced that comply with the terms and objective of use.
2. **Corrective And Preventive Action**, further to be abbreviated as **CAPA**, is the act of correction and prevention taken towards the findings of inspection. The CAPA document is a document resulting from such inspection, which will be delivered by the Registrant in order to follow up on the inspection results.
3. **Desktop Inspection** is an assessment of the implementation and fulfillment of GMP requirements in the facilities used to manufacture imported drugs, carried out through evaluation of the Pre-Inspection Document.
4. **Pre-Inspection Document** is a document regarding quality of the Producer that must be submitted by the Applicant in connection with the Desktop Inspection or before inspection is made of the facilities used to manufacture imported drugs.
5. **Inspection of Facilities Used to Manufacture Imported Drugs** is an inspection made in order to assess the compliance with GMP of the facilities used to manufacture the imported drugs as well as in the context of evaluating the validity after the Marketing Permit Number for the imported drugs is issued.
6. **Imported Drugs** are the drugs manufactured by a pharmaceutical company of another country as a finished product or in bulk, in the primary packaging that will be marketed in Indonesia.
7. **Stakeholder** is a party with interests in part or all of the process of inspecting the facilities used to manufacture the imported drugs.
8. **Applicant** is a domestic pharmaceutical company that already holds a pharmaceutical industry permit in accordance with the provisions of the laws and regulations in effect, that submits a request to register imported drugs.
9. **Producer** is a foreign pharmaceutical company that carries out part or all of the activities in manufacturing the imported drugs.
10. **Pharmaceutical Industry Master Document**, which shall be referred

toas DIIF, is a document containing specific information about the quality management and production activity policy and/or quality control over the manufacture of drugs, ingredients of the drug, conducted at the location and related activities in the surrounding buildings.

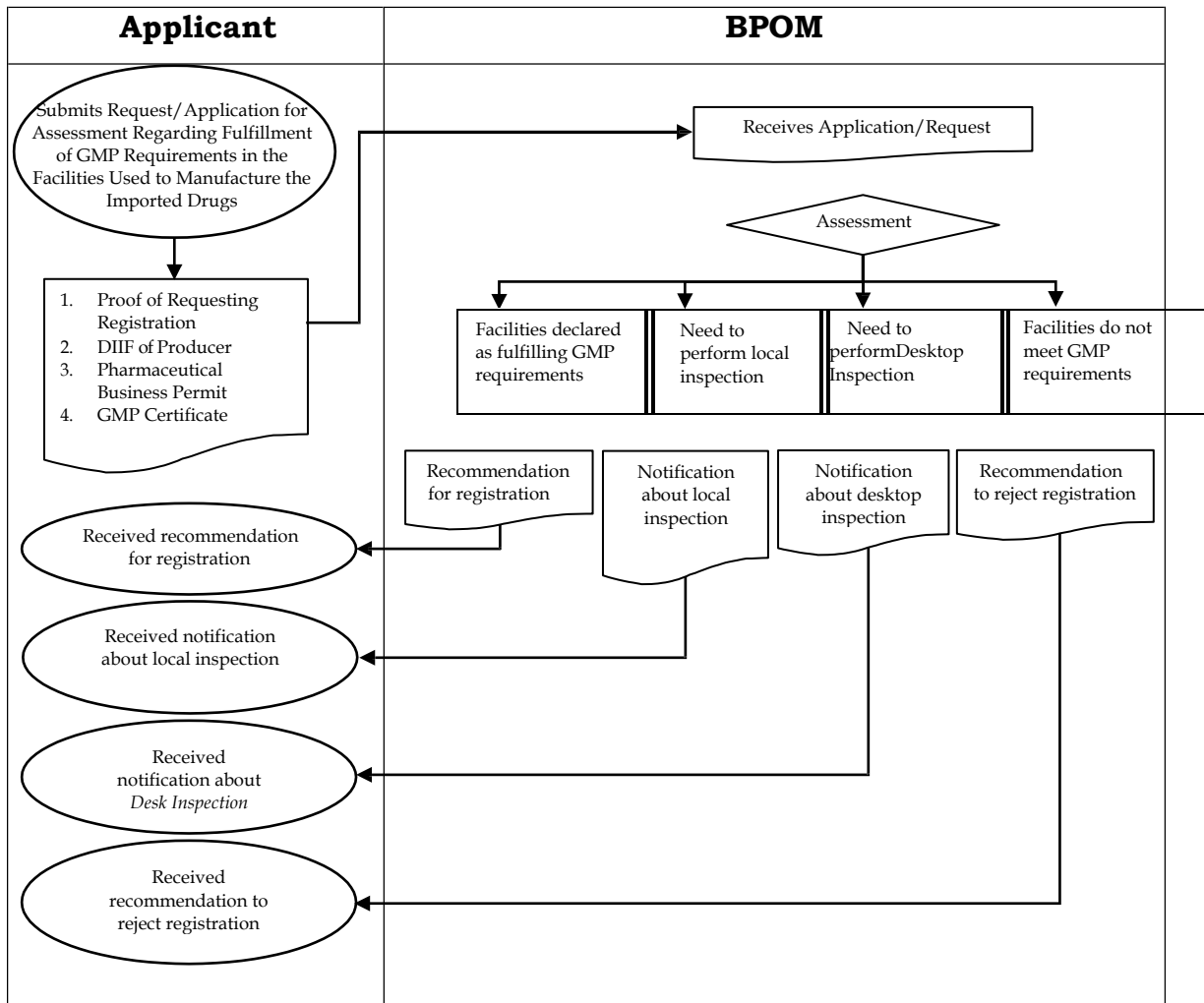
**PART TWO**  
**FRAMEWORK AND STANDARD PROCEDURE**  
**OF SERVICES**

**A. Framework of Procedures**

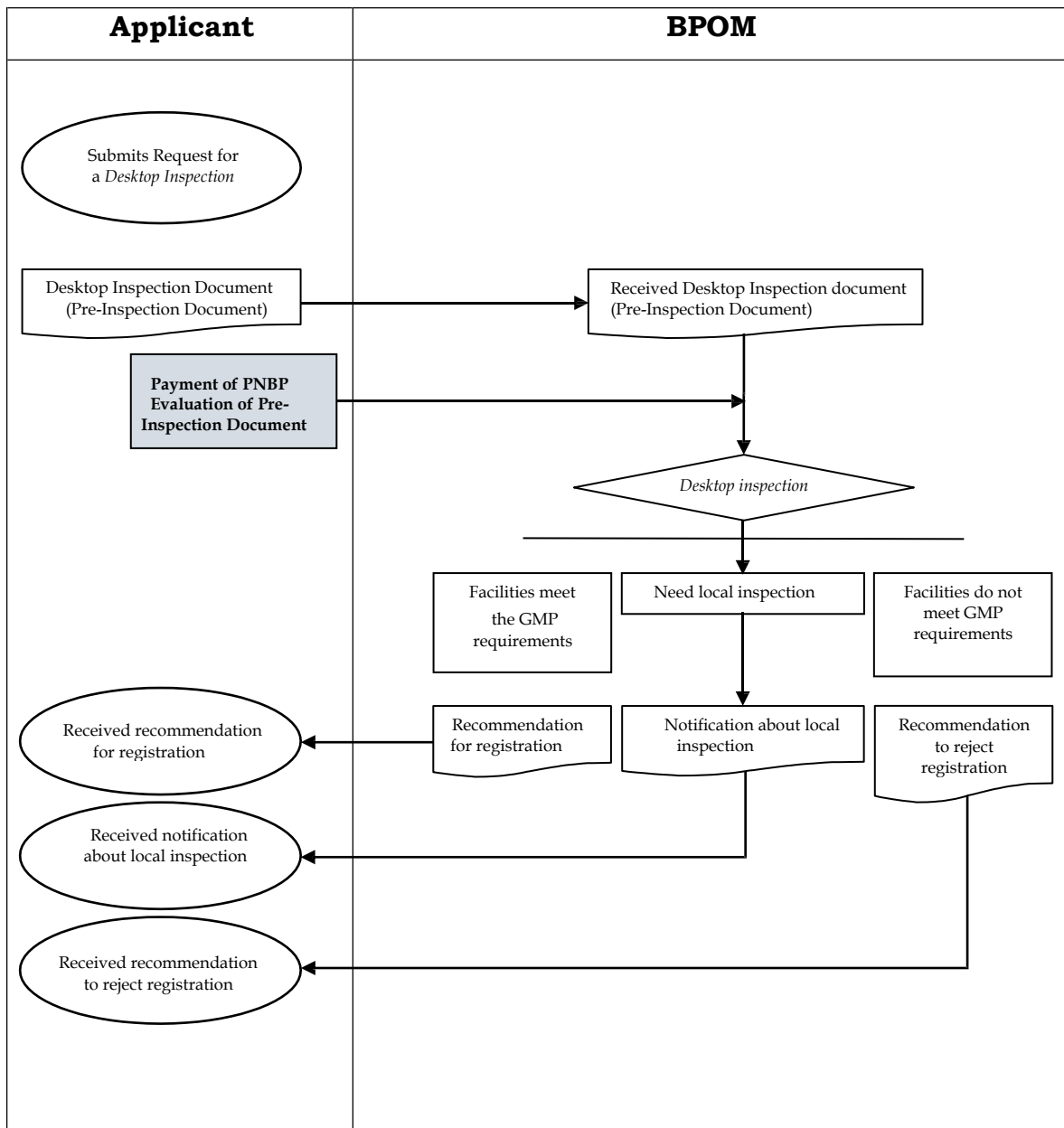
| <b>No.</b> | <b>Type of Service</b>   | <b>Time of Completion</b>                       | <b>Cost/Rate</b>                                   | <b>Service Product</b>  |
|------------|--|---|--|---|
| 1          | Assessment of the Imported Drug Registration Document in connection with fulfilling GMP                  | 15 days after the complete document is received |  | Notification of the Results of assessing fulfillment of GMP                   |
| 2          | Desktop Inspection   | 20 days after the complete document is received | According to PP Number 32 Year 2017                | Notification of Desk Inspection Results                                       |
| 3          | Follow-up to the Result of Inspecting Facilities for the Manufacture of Imported Drugs                   | 22 days after the inspection is conducted       | on the Types and Rate on the Types of PNBP at BPOM | Report on Inspection of the Facilities Used to Manufacture the Imported Drugs |
| 4          | Evaluation of CAPA towards the Result of Inspecting the Facilities for Manufacture of the Imported Drugs | 30 days for each submission of a CAPA document  |  | Letter of Response to CAPA, or a Closed Audit Report                          |

## B. Procedure of Services

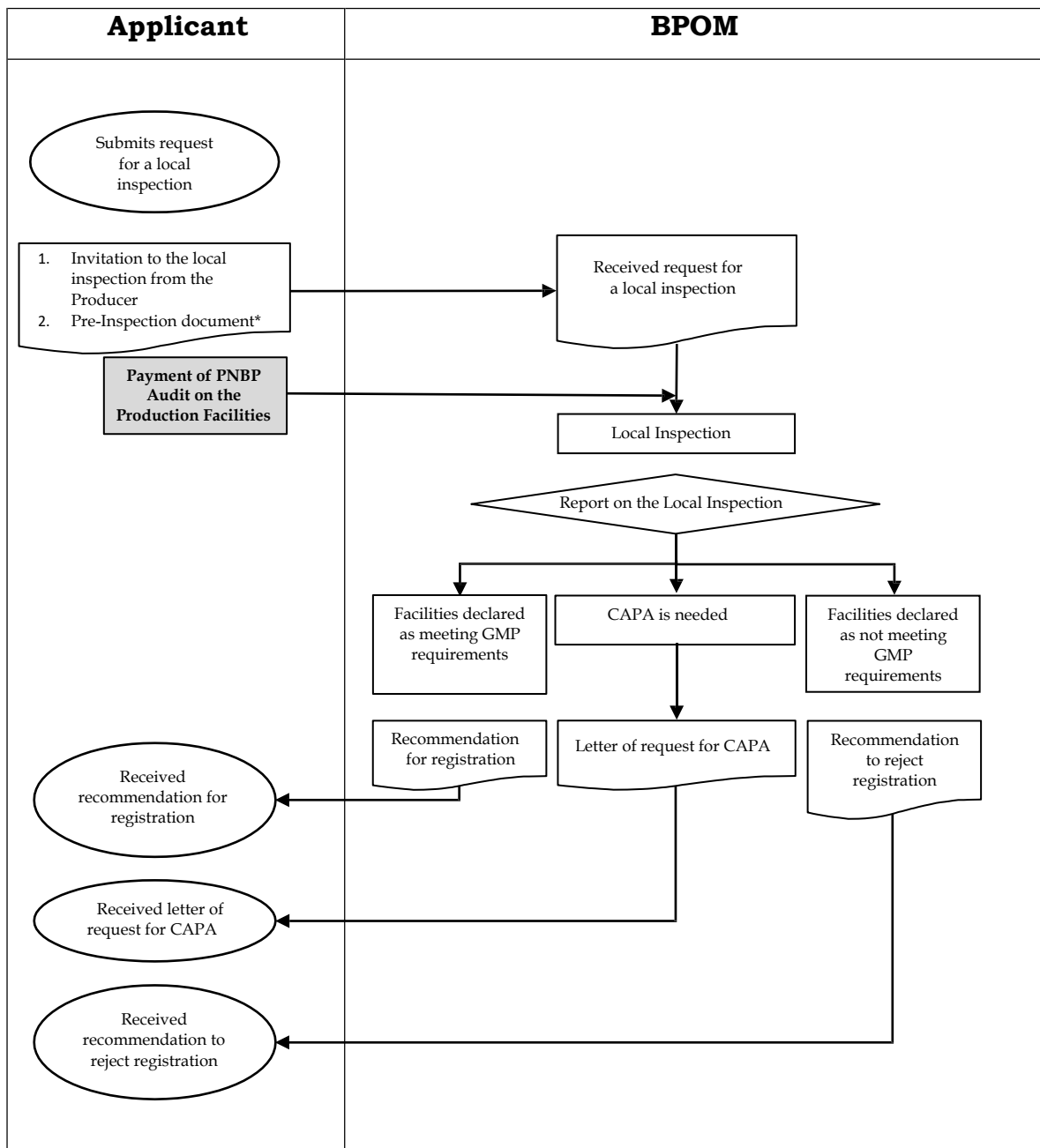
### a. Request for Assessment on Import Drugs Registration Document In Connection With Fulfilling GMP



## b. Request for Desktop Inspection

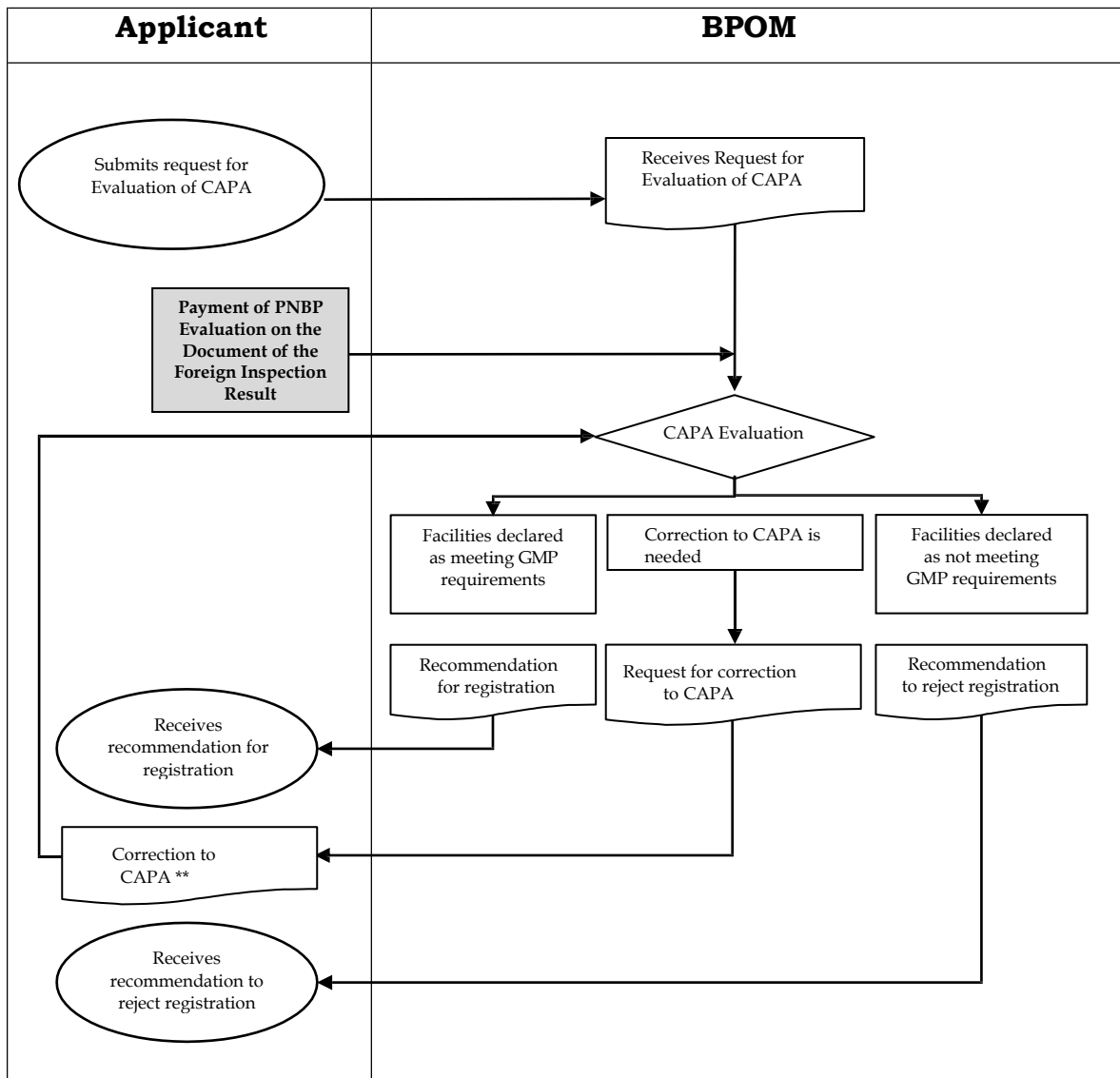


**c. Request for Inspection of the Imported Drug Manufacturing Facilities**



Note: \* Particularly for requests to inspect the drug manufacturing facilities which come from the process of requesting assessment on the documents for registration of imported drugs in connection with fulfilling GMP requirements (the pre-inspection document is submitted as a preparation document for the local inspection)

**d. Request for Evaluation of CAPA as the Result of Inspection on the Imported Drug Manufacturing Facilities**



Ket : \*\* If CAPA is still not appropriate after 2 (two) times correction and/or does not deliver CAPA in time for completion, then BPOM will issue a recommendation to reject registration of the imported drug concerned.

**C. Schedule of Services**

1. Service Counter

Monday–Thursday : 08.30 –16.00WIB Break  
: 12.00 – 13.00WIB  
Friday : 08.30 – 15.30WIB  
Break : 11.30 – 13.30WIB

2. Consultation Service

Monday–Friday : 08.30 –16.00WIB Break

: 12.00 – 13.00WIB

**D. Service Facilities and Infrastructure**

1. Service Room;
2. Service Desk;
3. Computer;
4. Waiting Room;
5. Suggestion Box;
6. Tools for Customer Satisfaction Survey;
7. Drinking Water;
8. Charging Box;
9. Queue System;
10. Lift;
11. Toilet;
12. Parking Lot;and
13. Nursing Room.

**E. Requirements**

1. Assessment of the Imported Drug Registration Document in connection with fulfilling GMP requirements
  - a. Administrative Documents
    - 1) Letter of Request / Application
    - 2) Statement by the Registrant regarding Completeness and Correctness of the Documents
    - 3) Proof of Submitting Registration
  - b. Technical Documents
    - 1) DIIF from Producer
    - 2) Pharmaceutical company license from the local country authorities;
    - 3) Valid GMP Certificate or other equivalent document issued by the local drug control authority and/or the drug control authority of another country; and
    - 4) Report on the latest inspection and any changes related to the production facilities of the product registered for at longest 2 (two) years, issued by the local drug control authority and/or the drug control authority of another country;
2. Desktop Inspection
  - a. Administrative Documents
    - 1) Letter of Request / Application

2) Statement regarding the Completeness and Correctness of Documents submitted by the Registrant

3) Proof of Payment of PNBP in accordance with the law

b. Technical Documents

Are pre-inspection documents submitted as a soft copy consisting of the following:

| No | Type of Document   | Form of Preparation                    |           |   |
|----|--|--|-----------|---|
|    |  | Tablet, Capsule, Cream, and Inhalation | Injection | Biological products (i.e. vaccine, blood product, bi-therapeutical product) |
| 1  | <i>Product Quality Review</i> of products registered in the last 2 years               | ✓                                      | ✓         | ✓   |
| 2  | Master Plan of Validation and realization of the MPV in the past year                  | ✓                                      | ✓         | ✓   |
| 3  | Protocol and Summary Report Validation of Filling In the Media in the last 1 year      | -                                      | ✓***      | ✓   |
| 4  | Analysis of Environmental Monitoring Trends and Result of Water Testing in last 1 year | ✓                                      | ✓         | ✓   |
| 5  | Fixed procedure for passing of the final product                                       | ✓                                      | ✓         | ✓   |
| 6  | History of recall/ withdrawal, sanction and defect in quality in past 3 years          | ✓                                      | ✓         | ✓   |

Ket: \*\*\* if the process of filling in the product is done using aseptic techniques

3. Inspection of the Manufacturing Facilities of Import Drugs
  - a. Administrative Documents
    - 1) Letter of Request /Application
    - 2) Proof of Paying PNBP in accordance with the law
  - b. Technical Document  
Pre-inspection document
4. Evaluation of CAPA to Result of Inspecting Import Drug Manufacturing Facilities
  - a. Administrative Documents
    - 1) Letter of Request
    - 2) Statement by the Registrant regarding the Completeness and Correctness of Documents
      - 1) Proof of Paying PNBP in accordance with the law
  - b. Technical Document  
CAPA document to the result of inspection of the facilities for manufacturing imported drugs, in accordance with the inspection report.

**F. Place of Services**

Public Service Building

Indonesian Food and Drug Authority

Jl. Percetakan Negara No.23, Central Jakarta 10560

## **SUB ATTACHMENT I.5**

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY NUMBER  
27 YEAR 2018  
REGARDING  
PUBLIC SERVICE STANDARDS WITHIN THE SCOPE OF  
THE INDONESIAN FOOD AND DRUG AUTHORITY

### **SERVICE STANDARDS FOR ISSUING APPROVAL TO USE DRUG PRODUCTION FACILITIES FOR NON-DRUG PRODUCTS**

#### **PART ONE INTRODUCTION**

##### **A. Legal Basis**

Circular of the Deputy for Control of Therapeutic Products and NAPZA (Narcotics, Psychotropic Drugs and Addictive Substances) Number ST.03.03.331.3.12.15.6452 dated 10 December 2015 regarding Implementation of the Policy to Use Drug Production Facilities For Non-Drugs.

##### **B. Purpose and Objective**

**The purpose of determining service standards** is to provide guidelines for organizing the services and provide a reference for stakeholders who wish to submit a request for approval to use the production facilities of drugs (medicine) together with non-drugs (traditional medicine and or health supplements and or cosmetics and or quasi-drugs).

**The objectives of service standards** are to:

- a. Increase the understanding of the stakeholders in the context of requesting approval to use the production facilities of drugs (medicine) together with non-drugs (traditional medicine and or health supplements and or cosmetics or quasi-drugs) in order to comply with the rules.
- b. Determine a reference/guidelines in the context of conducting evaluation of the approval to use the production facilities of drugs (medicine) together with non-drugs (traditional medicine and or health supplements and or cosmetics or quasi-drugs).

### C. Definition/General Meaning

1. **Good Manufacturing Practice**, which shall be referred to as **GMP**, is a method of manufacturing drugs and/or material for drugs that intends to ensure the quality of the drugs and/or substance produced so that they comply with the terms and objective of use.
2. **Certificate of Analysis**, or abbreviated as **COA**, is the result of analyzing the initial substance in terms of its chemical, physical and biological characteristics which is then stated descriptively and numerically according to the specifications.
3. **Pharmaceutical Company** is a corporate body that holds a license in compliance with provisions of the law to carry out activities in the manufacture of drugs or material for drugs.
4. **Drug** is a substance or ingredient or combination of ingredients including biological products that are used to influence or investigate the physiological system or pathological conditions in the framework of determining a diagnosis, for prevention, cure, recovery, and improvement of health, and contraception for humans.
5. **Non-Drug** is a preparation in the category of health supplements, traditional medicine, cosmetics and quasi-drugs.
6. **Pharmaceutical Grade** is a substance having a high level of purity and pharmaceutical quality in accordance with the requirements of pharmacopeia.
7. **GMP Certificate** is a legitimate document which is proof that the pharmaceutical company or facility implements Good Manufacturing Practice (GMP) when manufacturing drugs and/or material for drugs.
8. **Simplicia** is a natural substance used as medicine that has not been processed in any way whatsoever and, unless declared otherwise, is a substance that has been dried.
9. **Letter of Approval for the Joint Use of Facilities** is a valid document which serves as proof that the said pharmaceutical company has obtained a permit for the production of traditional medicines and or health supplements and or cosmetics and or quasi-drugs using production facilities that already meet GMP requirements, issued by the Deputy for Control of Drugs, Narcotics, Psychotropics, Precursors and Addictive Substances.

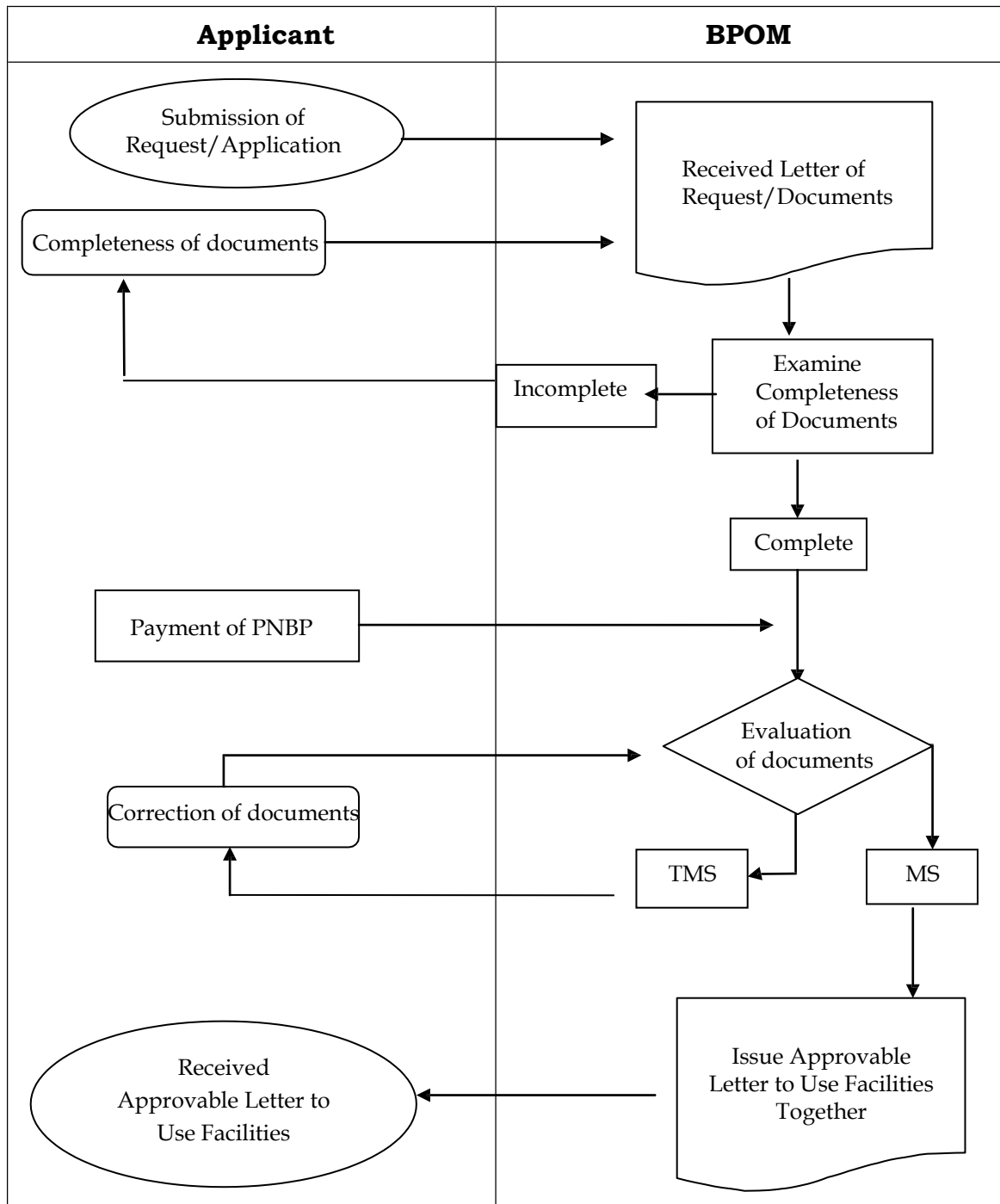
**PART TWO**  
**FRAMEWORK AND STANDAD PROCEDURE OF**  
**SERVICES**

**A. Framework of Procedures**

| <b>No.</b> | <b>Type of Service</b>  | <b>Time of Completion</b>                     | <b>Cost/Rate</b>   | <b>Service Product</b> |
|------------|---|---|--|------------------------|
| 1          | Request/Application for Approval to Use Production Facilities of Drugs Together With Non-Drugs (Traditional Medicine and or Health Supplement and or Cosmetics and or Quasi-Drugs | 20 days per form of preparation per commodity | According to PP Number 32 Year 2017 on the Types and Rate on Types of PNBP at BPOM |                        |

**B. Procedure of Services**

**Request/Application for Issuance of Approval to Use the Production Facilities of Drugs Together With Non-Drugs (Traditional Medicine and or Health Supplement andor Cosmetics and or Quasi-Drugs)**



### **C. Schedule of Services**

#### 1. Service Counter

Monday–Thursday : 08.30 –16.00WIB

Break : 12.00 – 13.00WIB

Friday : 08.30 – 15.30WIB

Break : 11.30 – 13.30WIB

#### 2. Consultation Service

Monday–Friday : 08.30 –15.30WIB Break

: 12.00 – 13.00WIB

### **D. Service Facilities and Infrastructure**

1. Service Room;
2. Service Desk;
3. Computer;
4. Waiting Room;
5. Suggestion Box;
6. Tools for Customer Satisfaction Survey
7. Drinking Water
8. Charging Box
9. Queue System;
10. Lift;
11. Toilet;
12. Parking Lot; and
13. Nursing Room.

### **E. Requirements**

1. Administrative Documents
  - a. Letter of Request/Application with a copy to the local Indonesian Food and Drug Authority /Center.
  - b. Proof of paying PNBP in accordance with the provisions of the law.
2. Technical Documents
  - a. New application
    - 1) New letter of request/application for the joint use of drug production facilities to manufacture non-drugs.
    - 2) Letter of approval to jointly use the production facilities owned (if any).

- 3) Photocopy of the most recent GMP Certificate, the facilities that will be used jointly (the GMP Certificate is pursuant to the form of preparation produced by the facilities and is still valid).
- 4) Data regarding the installed capacity, used capacity, and idle capacity of each production equipment that will be used jointly.
- 5) Data regarding the laboratory capacity, used capacity and idle capacity of each testing equipment that is used jointly.
- 6) Written Statement of the QA Manager or authorized personnel made with affixed duty stamp stating that:
  - The idle production capacity is sufficient for producing non-therapeutic products.
  - The testing of non-therapeutic products does not affect the testing of therapeutic products.
- 7) Layout of the warehouse showing the location of storing the raw materials, packaging material, and the finished products, where therapeutic products and non-therapeutic products are stored separately.
- 8) Matrix on data of non-drug products:
  - that were manufactured pursuant to the letter of approval issued for the said facility and according to the form of preparation, stating: the name of the product, number and date of the Marketing Permit, composition (including specifications of the raw materials\*), and the qualitative and quantitative methods of analysis, and a compendial reference.
  - that will be produced according to the request at the facility for the type/form of preparation, stating: name of product, composition (including specifications of the raw materials\*), and the qualitative and quantitative methods of analysis, and a compendial reference.

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\*) Specification of raw material

- Conditions of the active raw material:
  - ✓ Is not a simplicia, but an extract, it can be dry or wet, and
  - ✓ Has specifications and a quality standard that can be tested qualitatively and quantitatively

- Condition of auxiliary raw material: Meets compendial requirements.

- 9) Matrix on data of the production equipment used jointly, which includes: name and ID of the equipment for each process, number of the document on cleaning procedure, product marker.
- 10) Validation Master Plan which includes the cleaning validation policy.
- 11) Fixed procedure for cleaning the equipment used jointly.
- 12) Fixed procedure for cleaning the rooms used jointly.
- 13) Protocol for validation of cleaning the equipment used jointly.
- 14) Risk assessment/ review to determine marker which includes the risk factor of the non-drug products to be manufactured jointly at the facility, not limited to the smallest therapeutic dose, toxicity, and solubility.
- 15) Protocol and report on validating the method of analyzing the product marker which includes a *recovery swab test*.

b. Request for extension

- 1) Letter of request to extend the joint use of drug production facilities for the manufacturing of non-drugs (can be submitted at the same time as a request for extension of the GMP Certificate).
- 2) Photocopy of the Approval for Joint Use of Drug Production Facilities To Manufacture Non-Drugs for which the extension is requested.
- 3) Photocopy of the latest GMP Certificate of the facility jointly used (The GMP Certificate is pursuant to the form of preparation at the facility for which extension is requested, and is still valid).
- 4) Matrix on data of the non-drug products produced at the drug production facility pursuant to the form of the preparation, which includes: name of the product, number and date of the Marketing Permit, composition, and qualitative and quantitative methods of analysis.
- 5) Matrix on data of the production equipment used jointly, includes: name and ID of the equipment used in each stage of the process, number of the document on cleaning procedures, product marker.
- 6) Fixed procedure for cleaning the equipment used jointly.

- 7) Fixed procedure for cleaning the rooms used jointly.
- 8) Risk assessment/ review to determine markers which covers the risk factors of the non-drug products that will be produced at the facility, not limited to the smallest therapeutic dose, toxicity, and solubility.
- 9) Protocol and report on validation of cleaning the equipment that was used jointly.
- 10) Protocol and report on validation of the method for analyzing product markers, which includes *recovery swab test*.

**F. Place of Service**

Public Service Building

Indonesian Food and Drug Authority

Jl. Percetakan Negara No.23, Central Jakarta 10560

## **SUB-ATTACHMENT I.6**

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY  
NUMBER 27 YEAR 2018  
REGARDING  
PUBLIC SERVICE STANDARDS WITHIN THE SCOPE OF  
THE INDONESIAN FOOD AND DRUG AUTHORITY

**SERVICE STANDARDS FOR  
ISSUING APPROVAL TO USE THE PRODUCTION FACILITIES FOR  
TRADITIONAL MEDICINE JOINTLY WITH QUASI-DRUGS, COSMETICS,  
AND PROCESSED FOODS**

**PART ONE  
INTRODUCTION**

### **A. Legal Basis**

1. Regulation of the Minister of Health Number 26 Year 2018 on Electronically Integrated Services to Obtain Business Licenses in the Health Sector;
2. Regulation of the Chairperson of the Indonesian Food and Drug Authority of the Republic of Indonesia Number HK.03.1.23.06.11.5629 Year 2011 on Technical Requirements for Good Manufacturing Practice for Traditional Medicine, Drugs and Food, Year 2011;
3. Regulation of the Chairperson of the Indonesian Food and Drug Authority of the Republic of Indonesia Number 35 Year 2013 on Procedure for Certification of Good Manufacturing Practice for Traditional Medicines.

### **B. Purpose and Objective**

**The purpose of determining service standards** is to set guidelines for organizing services and to provide a reference for the stakeholders who intend to submit a request/application for approval to use the production facilities of traditional medicine jointly with non-traditional medicines (quasi-drugs and or cosmetics and or food).

**The objective of service standards is:**

- a. To increase the understanding of the stakeholder in the context

of requesting approval to jointly use the production facilities of traditional medicine together with non-traditional medicines (quasi drugs and or cosmetics and or food) in order to comply with provisions.

- b. Provide a reference/guidelines in the context of conducting evaluation on the approval for using the production facilities of traditional medicine together with non-traditional medicines (quasi drugs and or cosmetics and or food).

### **C. Definitions/General Meaning**

1. **Good Manufacturing Practice for Traditional Medicine**, that can be abbreviated as **GMP-TM**, is the method of manufacturing traditional medicine that aims to make sure that the quality of the traditional medicine produced is in accordance with the terms and objective of use.
2. **Deputy II** is the Deputy for Control of Traditional Medicine, Health Supplements, and Cosmetics.
3. **Traditional Medicine Industry**, which shall be referred to as TMI, is a company that produces all kinds of traditional medicine.
4. **Small Traditional Medicine Company**, or STM, is an enterprise that produces all forms of traditional medicine except tablets, effervescent tablets, suppositories and soft capsules.
5. **Micro Traditional Medicine Company**, or MTM, is an enterprise that only produces traditional medicine in the form of *param, tapel, pilis*, liniment and finely sliced herbal ingredients.
6. **Certificate of Analysis**, abbreviated as COA, is the result of analyzing the initial substance in terms of chemical, physical and biological characteristics which are stated descriptively and numerically according to the specifications.
7. **Traditional Medicine** is a substance or mixture of substances which can come from plants, animals, minerals, galenic preparations, or a combination of these, that traditionally have been used as medication based on experience.
8. **Non-Traditional Medicine** are all preparations that fall into the category of quasi-drugs, cosmetics, and foods.
9. **GMP-TM Certificate** is a valid document which is proof that the traditional medicine company and/or company that extracts natural

ingredients complies with GMP-TM requirements in producing one of the types of traditional medicinal preparations.

10. **Certificate of GMP-TM in Stages** is a valid document which proves that the Small TM Company / Micro TM Company applies the aspects of GMP-TM in stages when producing a type of traditional medicine.
11. **GMP-TM in Stages** is the application of GMP-TM aspects in stages by the Small TM Company / Micro TM Company.
12. **Simplicia** is a natural substance used as medicine that has not undergone any kind of processing whatsoever and unless stated otherwise is a substance that has been dried.
13. **Letter of Approval for Joint Use Of Facilities** is a valid document which serves as proof that the traditional medicine company / small traditional medicine company / micro traditional medicine company has already obtained a permit for the production or testing of quasi-drugs and or cosmetics and or food at the production facility or testing facility that already meets the GMP-TM requirements issued by the Deputy for Control of Traditional Medicine, Health Supplements, and Cosmetics.

**PART TWO**  
**FRAMEWORK AND STANDARD PROCEDURE**  
**OF SERVICES**

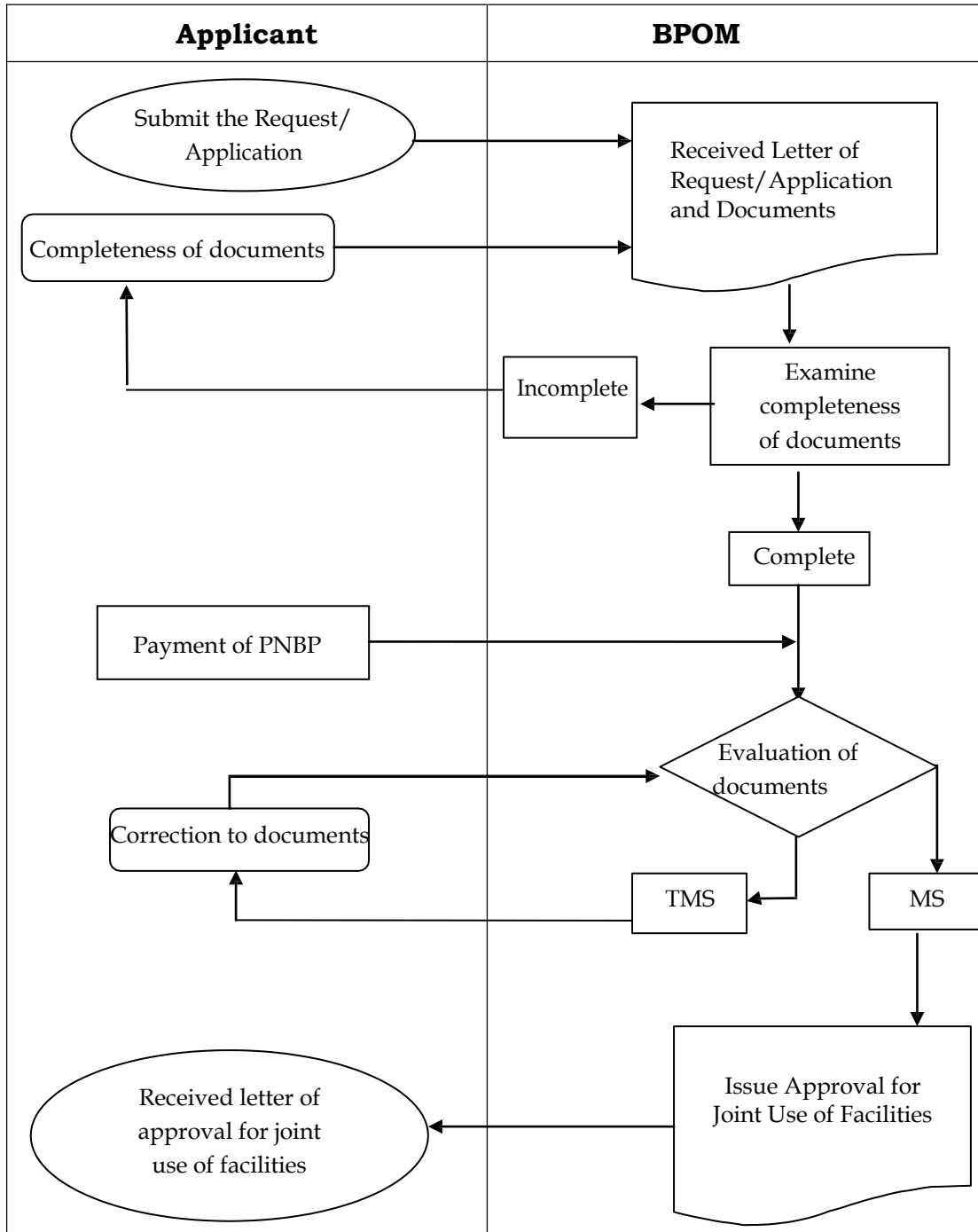
**A. Framework of Procedures**

| <b>No.</b> | <b>Type of Service</b>  | <b>Time of Completion</b>                          | <b>Cost/Rate</b>   | <b>Service Product</b>  |
|------------|---|--|--|---|
|            | Request/Application for Issuance of Approval for the Joint Use of Facilities for Production and or Testing of Traditional Medicine Together With Non Traditional Medicine (quasi drugs and or cosmetics and or foods) for the Traditional Medicine Industry (TMI)         | 20 days for each form of preparation per commodity | According to PPNumber32 Year 2017 on the Types and Rate on Types of PNPB at BPOM | Letter of Approval for Joint Use of Facilities or Letter Requesting Corrections |
| 2          | Request/Application for Issuance of Approval for the Joint Use of Facilities for Production and or Testing of Traditional Medicine Together with Non Traditional Medicines (Quasi Drugs and or Cosmetics and or Foods) for the Small/Micro Traditional Medicine Companies |  |  |   |
|            | a. Inspection of the GMP-TM Stages  | 10 days from the date of request for inspection    | According to PPNumber32 Year 2017 on the Types                                   | Letter of Approval for Joint Use of Facilities or Letter                        |
|            | b.Evaluation of the Result of Inspecting Certification  | 5 days from the day of inspecting certification    | and Rate on Types of PNPB at BPOM  | Requesting Corrections  |

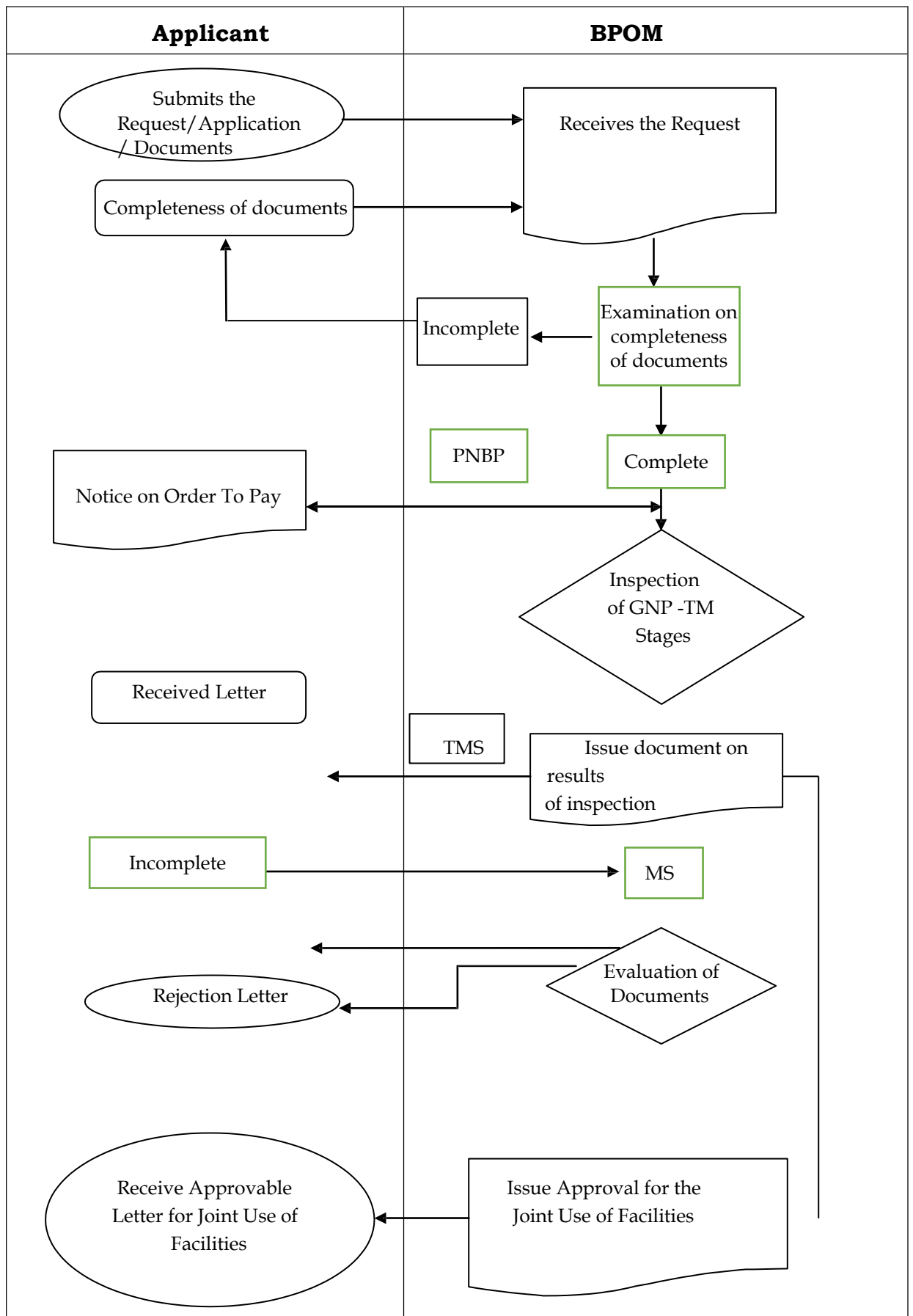
|  |  |                             |  |  |
|--|--|-----------------------------|--|--|
|  | c. Evaluation of CAPA                                      | 15 days from receiving CAPA |  |  |
|  | d. Issue the Leter of Approval for Joint Use of Facilities | 5 days since closed CAPA    |  |  |

**B. Procedure of Services**

- a.** Request/Application for Issuance of Approval for the Joint Use of Facilities for Production and or Testing of Traditional Medicine Together With Non Traditional Medicine (quasi drugs and or cosmetics and or foods)



- b.** Request/Application for Issuance of Approval for the Joint Use of Facilities for Production and or Testing by Small/Micro TM Company Together with Non Traditional Medicine (quasi drugs and or cosmetics and or foods)



### **C. Schedule of Services**

#### 1. Service Counter

Monday–Thursday : 08.30 –16.00WIB

Break : 12.00 – 13.00WIB

Friday : 08.30 – 15.30WIB

Break : 11.30 – 13.30WIB

#### 2. Consultation Services

Monday–Friday : 08.30 –15.30WIB

Break : 12.00 – 13.00WIB

### **D. Service Facilities and Infrastructure**

1. Service Room;
2. Service Desk;
3. Computer;
4. Waiting Room;
5. Suggestion Box;
6. Tools for Customer Satisfaction Survey
7. Drinking Water
8. Charging Box
9. Queue System;
10. Lift;
11. Toilet;
12. Parking Lot; and
13. Nursing Room.

### **E. Requirements**

1. Letter of Request for Issuance of Approval to Use The Production Facilities of Traditional Medicines Jointly With Non Traditional Medicines (quasi-drugs and or cosmetics and or foods) to the Traditional Medicine Company.
  - a. Administrative Documents
    - 1) Letter of Request with a copy to the local Drug and Food Control Agency / Center
    - 2) Proof of paying PNBP in accordance with provisions of the law
  - b. Technical Documents
    - 1) GMP-TM Certificate of the facility that will be jointly used.

- 2) Formula of the product that will be produced at the joint facility.
  - 3) Statement of the Person Responsible that:
    - a) There is still excess capacity to produce non-traditional medicines
    - b) The active raw material and auxiliary material to be used must have (at least) pharmaceutical grade / food grade
    - c) Production of the non-traditional medicines shall not affect the implementation of tests to ensure quality of the products and shall not influence the storage of the traditional medicines.
  - c. Planning for the production of traditional medicine and non-traditional medicines that can prevent any possibility of cross-contamination.
  - d. Fixed procedure for cleaning the equipment and the rooms to be used for the joint production.
  - e. Protocol to validate the cleaning of equipment including the method of analyzing used in validating the cleaning.
  - f. Fixed procedure and layout for the storage of raw materials and packaging material as well as the finished products of both the traditional medicines and non-traditional medicines that will be produced together.
2. Letter of Request for Issuance of Approval to Use the Production Facilities and or Test Facilities of traditional medicine together with non-traditional medicines (quasi drugs and or cosmetics and or foods) to the Small / Micro Traditional Medicine Companies.
- a. Administrative Documents
    - 1) Letter of Request with a copy to the local Food and Drug Authority / Center
    - 2) Proof of having paid PNBP in accordance with the law.
  - b. Technical Documents
    - 1) Certificate of GMP-TM in Stages – Stage 2 of the facility to be used together.
    - 2) Formula of the product to be produced at the joint facility
    - 3) Statement of the Person Responsible that:
      - a) There is still excess capacity to produce non-traditional medicines
      - b) The active raw material and auxiliary material to be used must have (at least) pharmaceutical grade / food grade
      - c) Production of the non-traditional medicines shall not affect the

implementation of tests to ensure quality of the products and shall not influence the storage of the traditional medicines.

- c. Planning for the production of traditional medicine and non-traditional medicines that can prevent any possibility of cross-contamination.
  - d. Fixed procedure for cleaning the equipment and the rooms to be used for the joint production.
  - e. Protocol to validate the cleaning of equipment including the method of analyzing used in validating the cleaning.
  - f. Fixed procedure and layout for the storage of raw materials and packaging material as well as the finished products of both the traditional medicines and non-traditional medicines that will be produced together.
3. Letter of Request for Issuance of Approval to Use the Testing Facilities of traditional medicine together with non-traditional medicines (quasi drugs and or cosmetics and or foods) to the Small / Micro Traditional Medicine Companies.
- a. Administrative Documents
    - 1) Letter of Request with a copy to the local Food and Drug Authority / Center
    - 2) Proof of having paid PNBP in accordance with the law.
  - b. Technical Documents
    - 1) Certificate of GMP-TM in Stages – Stage 2 of the facility to be used together.
    - 2) Statement of the Person In Charge that there is still excess capacity to test non-traditional medicines.
  - c. Planning for the testing of traditional medicine and non-traditional medicines that can prevent any possibility of cross-contamination.
  - d. Fixed procedure for cleaning the equipment and the rooms to be used for the joint production.
  - e. Protocol to validate the cleaning of equipment including the method of analyzing used in validating the cleaning.

#### **F. Validity of Certificate**

Pursuant to the period of validity of the certificate used at the time of requesting Joint Use of the Facilities.

**G. Place of Services**

Public Service Building

Indonesian Food and Drug Authority

Jl. Percetakan Negara No.23, Central Jakarta 10560

## **SUB-ATTACHMENT I.7**

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY NUMBER  
27 YEAR 2018  
REGARDING  
PUBLIC SERVICE STANDARDS WITHIN THE SCOPE OF  
THE INDONESIAN FOOD AND DRUG AUTHORITY

**SERVICE STANDARDS  
TO REQUEST GMP CERTIFICATION**

**PART ONE  
INTRODUCTION**

**A. Legal Basis**

1. Law Number 36 Year 2009 on Health;
2. Government Regulation Number 72 Year 1998 on the Safety of Pharmaceutical Preparations;
3. Government Regulation Number 32 Year 2017 on the Types and Rate on Types of Non-Tax State Revenue at the Indonesian Food and Drug Authority;
4. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.23.10.11.08481 Year 2011 on the Criteria and Procedure for Drug Registration as amended by the Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 3 Year 2013;
5. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.33.12.12.8195 Year 2012 on Applying the Guidelines for Good Manufacturing Practices;

**B. Purpose and Objective**

**The purpose of determining service standards is** to provide guidelines for the provider of services and a reference for the Pharmaceutical Companies in submitting their request for issuance of GMP Certification.

**The objective of service standards is to:**

- a. Increase the understanding of the pharmaceutical company that intends to submit GMP Certification so that it is in accordance with

the provisions of the law.

- b. Establish a reference/guidelines for issuing Certification of Good Manufacturing Practice (GMP) for the Finished Products.

### C. Definition/General Meaning

1. **Applicant** is the pharmaceutical company registered in Indonesia that intends to export goods/commodities to places outside the territory of Indonesia.
2. **Certification of Applying Good Manufacturing Practice (GMP)** is a valid and legal document which serves as proof that the said pharmaceutical company fulfills the requirement of GMP, and which is required for export.

## PART TWO

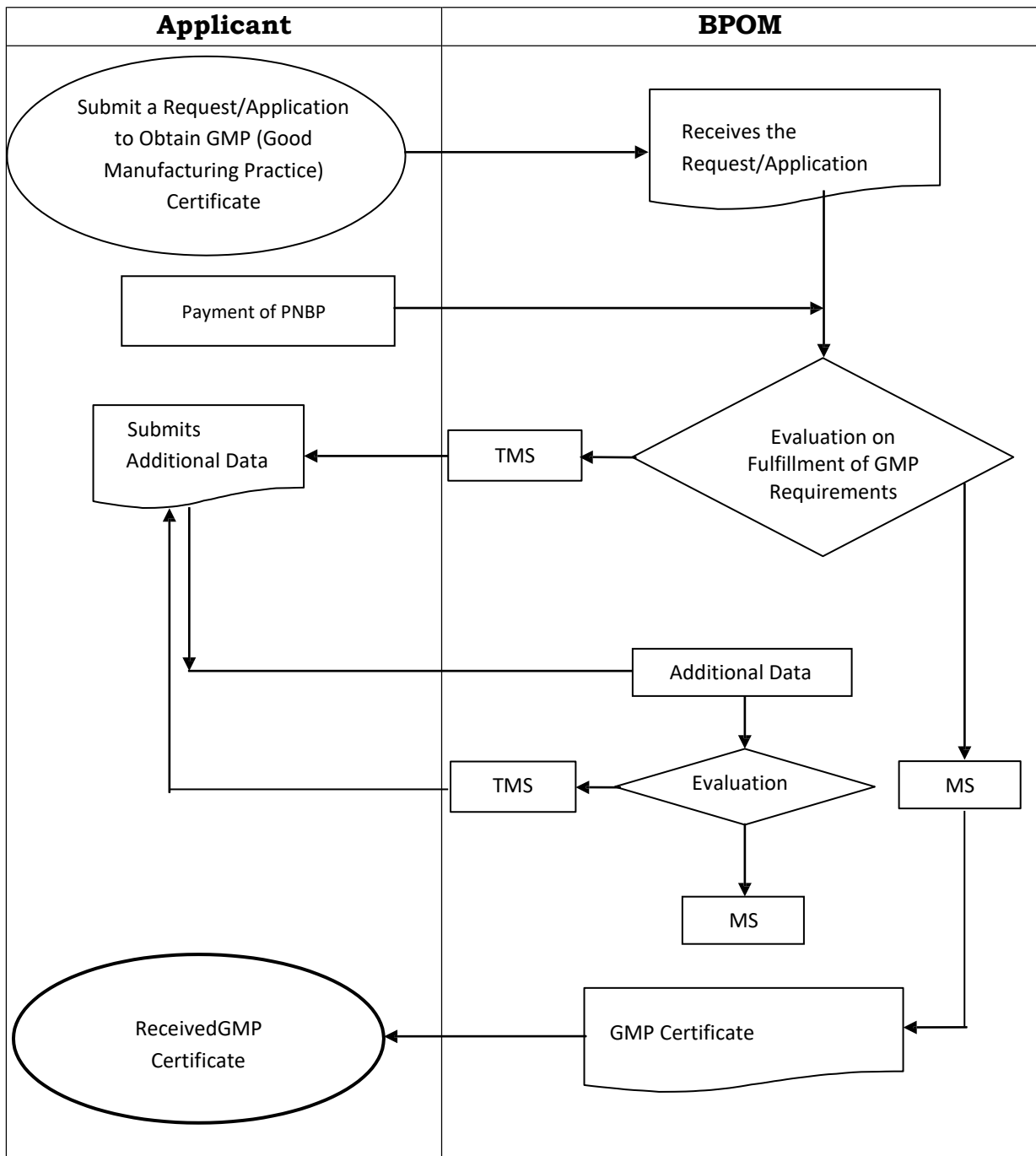
### FRAMEWORK AND STANDARD PROCEDURE OF SERVICES

#### A. Framework of Procedures

| No. | Type of Service   | Time of Completion | Cost/Rate  | Service Product |
|-----|---|--------------------|--|-----------------|
| 1   | Application to Obtain Certification of Implementing Good Manufacturing Practice (GMP) | 2 days             | According to PP Number 32 Year 2017 on Types and Rate on the Types of PNBP at BPOM | GMP Certificate |

## B. Procedure of Services

### Application for GMP (Good Manufacturing Practice) Certificate



### **C. Schedule of Services**

1. Service Counter
  - Monday–Thursday : 08.30–16.00
  - Break : 12.00 –13.00
  - Friday : 08.30 –15.30
  - Break : 11.30 –13.30
2. Consultation Services
  - Monday–Thursday : 09.00 –12.00

### **D. Service Facilities and Infrastructure**

1. Service room;
2. Service desk;
3. Computer;
4. Waiting room;
5. Suggestion box;
6. Tools for Customer Satisfaction Survey;
7. Drinking water;
8. Charging box;
9. Queue system;
10. Lift;
11. Toilet;
12. Parking lot; and
13. Nursing room.

### **E. Requirements**

- a. Administrative Documents
  - 1) Application Form requesting a GMP Certificate
  - 2) Photocopy of the Pharmaceutical Industry Permit
- b. Technical Documents
  - 1) Photocopy of GMP Certificate for the preparation that will be exported
  - 2) Photocopy of cooperative agreement for toll products

### **F. Place of Services**

Public Service Building  
Indonesian Food and Drug Authority  
Jl. Percetakan Negara No.23, Central Jakarta 10560

## **SUB-ATTACHMENT I.8**

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY  
NUMBER 27 YEAR 2018  
REGARDING  
PUBLIC SERVICE STANDARDS WITHIN THE SCOPE OF  
THE INDONESIAN FOOD AND DRUG AUTHORITY

**SERVICE STANDARDS FOR  
APPROVAL OF DESIGNS FOR THE ADVERTISEMENT OF DRUGS,  
TRADITIONAL MEDICINES, HEALTH SUPPLEMENTS,  
QUASI DRUGS, AND PROCESSED FOODS**

**PART ONE  
INTRODUCTION**

**A. Legal Basis**

1. Law Number 36 Year 2009 on Health;
2. Law Number 18 Year 2012 on Food;
3. Government Regulation Number 72 Year 1998 on The Safety of Pharmaceutical Preparations;
4. Government Regulation Number 69 Year 1999 on Labels and Food Advertisements;
5. Government Regulation Number 32 Year 2017 on The Types and Rate on Types of Non-Tax State Revenue at the Indonesian Food and Drug Authority;
6. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.00.05.41.1384 Year 2005 regarding The Criteria and Procedure for Requesting Approval for Traditional Medicines, Standardized Herbal Medicine, and Phytopharmaca;
7. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.00.06.1.52.6635 Year 2007 regarding Prohibition to Include Information About Being Free from Food Additives on the Label and Advertisement of Food;
8. Regulation of the Minister of Health Number 1010/Menkes/Per/XI/2008 on Drug Registration as amended by the Regulation of the Minister of Health Number 1120/MenKes/Per/XI/2008;
9. Regulation of the Minister of Health Number 1787/Menkes/Per/XII/2010 Year 2010 on Health Service

Advertisements and Publications;

10. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.23.11.11.09909 Year 2011 on Control Over Claims in Labels and Advertisements of Processed Foods;
11. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.5.12.11.09955 Year 2011 on Registration of Processed Foods;
12. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.5.12.11.09956 Year 2011 on Procedure for Registration of Processed Foods;
13. Regulation of the Minister of Health Number 007 Year 2012 on Registration of Traditional Medicines;
14. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 2 Year 2016 Technical Guidelines for Control Over Processed Food Advertising;
15. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 8 Year 2017 on Guidelines for Control Over Drug Advertising;
16. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 24 Year 2017 on Criteria and Procedure of Drug Registration;
17. Decision of the Minister of Health Number 386/Menkes/SK/IV/1994 Year 1994 on Guidelines for Advertising OTC Drugs, Traditional Medicine, Health Equipment, Cosmetics, Household Health Supplies, and Food and Drinks;
18. Decision of the Chairperson of the Indonesian Food and Drug Authority Number HK 00.05.3.02706 Year 2002 on Drug Promotion;
19. Decision of the Chairperson of the Indonesian Food and Drug Authority Number HK.00.05.4.0155 Year 2003 on Special Labeling and Advertising of Diarrhea Medicines;
20. Decision of the Chairperson of the Indonesian Food and Drug Authority Number HK.00.05.4.2411 Year 2004 on Basic Provisions for Grouping and Labelling Drugs Made from Natural Ingredients of Indonesia;
21. Decision of the Chairperson of the Indonesian Food and Drug Authority Number HK.00.05.23.3644 Year 2004 on Basic Provisions for Control of Food Supplements;

## **B. Purpose and Objective**

**The purpose of determining service standards** is to serve as guidelines for the providers of services and a reference for the business players who wish to submit a request for approval on the design of advertisements for drugs, traditional medicine, health supplements, quasi drugs, and processed foods.

**The objective of service standards** is to:

- a. Increase the understanding of the business actors in the context of requesting approval on the design of advertisements for drugs, traditional medicine, health supplements, quasi drugs, and processed foods.
- b. Establish a reference/guidelines in the context of providing service for the requests for approval on the design of advertisements for drugs, traditional medicine, health supplements, quasi drugs, and processed foods.

## **C. Definition/General Meaning**

1. **Advertisement (Ad)** is any information or statement about a product in the form of a picture, writing, or other form through various methods for the marketing and or trade of a product.
2. **Claim** is any form of description that declares, suggests or indirectly states a certain characteristic of a food with regard to its origin, nutritional content, nature, production, processing, composition or other quality factor.
3. **Product Information** is detailed information about a product that has been approved by the Indonesian Food and Drug Authority, concerning the efficacy, safety, instructions for use and other information considered necessary, written as a summary of the product characteristics/brochure and product information for patients.
4. **Marketing Permit** is a form of approval for the registration of drugs, traditional medicines and health supplements so they can be marketed in Indonesia.
5. **Approvable Letter for Registration** is approval on the results of assessing a processed food, issued by the Indonesian Food and

Drug Authority in the context of marketing processed foods.

6. **Food Registration Number** is the number given to a processed food product for the marketing of said product, stated in the Approvable Letter for Registration.
7. **Drug** is a manufactured medicine, including biological products, which is a substance or mixture of substances used to influence or to investigate the physiological system or pathological conditions in order to determine a diagnosis, or prevention, healing, recovery, improvement of health, and contraception for humans.
14. **Traditional Medicine** is a substance or mixture of substances such as from plants, animals, minerals, galenic preparations or a combination of such ingredients that have, from generation to generation, been used for medicinal purposes, and can be applied according to the norms of the community.
15. **Health Supplement** is a product meant to fulfill the need for nutrients, to maintain, increase and/or improve the health function; it has nutritious value and/or physiological effect, contains one or more ingredients which can be vitamins, minerals, amino acids and/or non-plant ingredients that can be combined with plant ingredients.
10. **Quasi drug** is a preparation that contains active substances and has a pharmacological effect to overcome minor ailments.
11. **Food** is anything that comes from biological sources and water, which is either processed or not processed, meant to be food or drinks for human consumption, including food additives, raw materials for food, and other substances used in the process of preparing, processing, and or making food or drinks.
12. **Processed Foods** are food and drinks which are the result of processing using certain methods with or without adding substances.
13. **Applicant** is any drug company, or business undertaking in traditional medicines, health supplements, and processed foods or an importer of drugs, traditional medicines, health supplements and processed foods as the holder of a marketing permit or food registration number.
14. **Ad Meeting** is a meeting between the Indonesian Food and Drug Authority and the Ad Assessment Team to discuss the advertising

of a drug, traditional medicine, health supplement, and processed food before it is marketed.

15. **Rejection Letter** is a letter rejecting the design of an advertisement proposed for a drug, traditional medicine, health supplement and processed food, because the concept of the advertisement does not meet the required provisions.
16. **Correction Letter** is a letter requesting correction and or improvement to be made in the design of the advertisement for a drug, traditional medicine, health supplement, and processed food. The design of the ad conceptually meets the provisions, however in several aspects (claims, picture, information, etc.) some correction is needed.
17. **Order To Pay (*Surat Perintah Bayar*)**, which herein shall be abbreviated as **SPB**) is a letter to pay the costs of evaluating the advertisement of a drug, traditional medicine, health supplement and processed food based on the Government Regulation (PP) Number 32 Year 2017 on the Types and Rate on Types of PNBPN at BPOM, in a sum according to the amount of products and version of the ad proposed.
18. **Letter of Approval** is a letter stating approval to the design of an advertisement for a drug, traditional medicine, health supplement and processed food that meets the required provisions.
19. **Ad Assessment Team** is a group of persons consisting of experts in their field related to assessment of advertisements for drugs, traditional medicines, health supplements and processed foods, who are appointed by Decision of the Chairperson of the Indonesian Food and Drug Authority and assigned to deliberate and give their recommendations based on the result of evaluating the advertisement in accordance with their expertise.

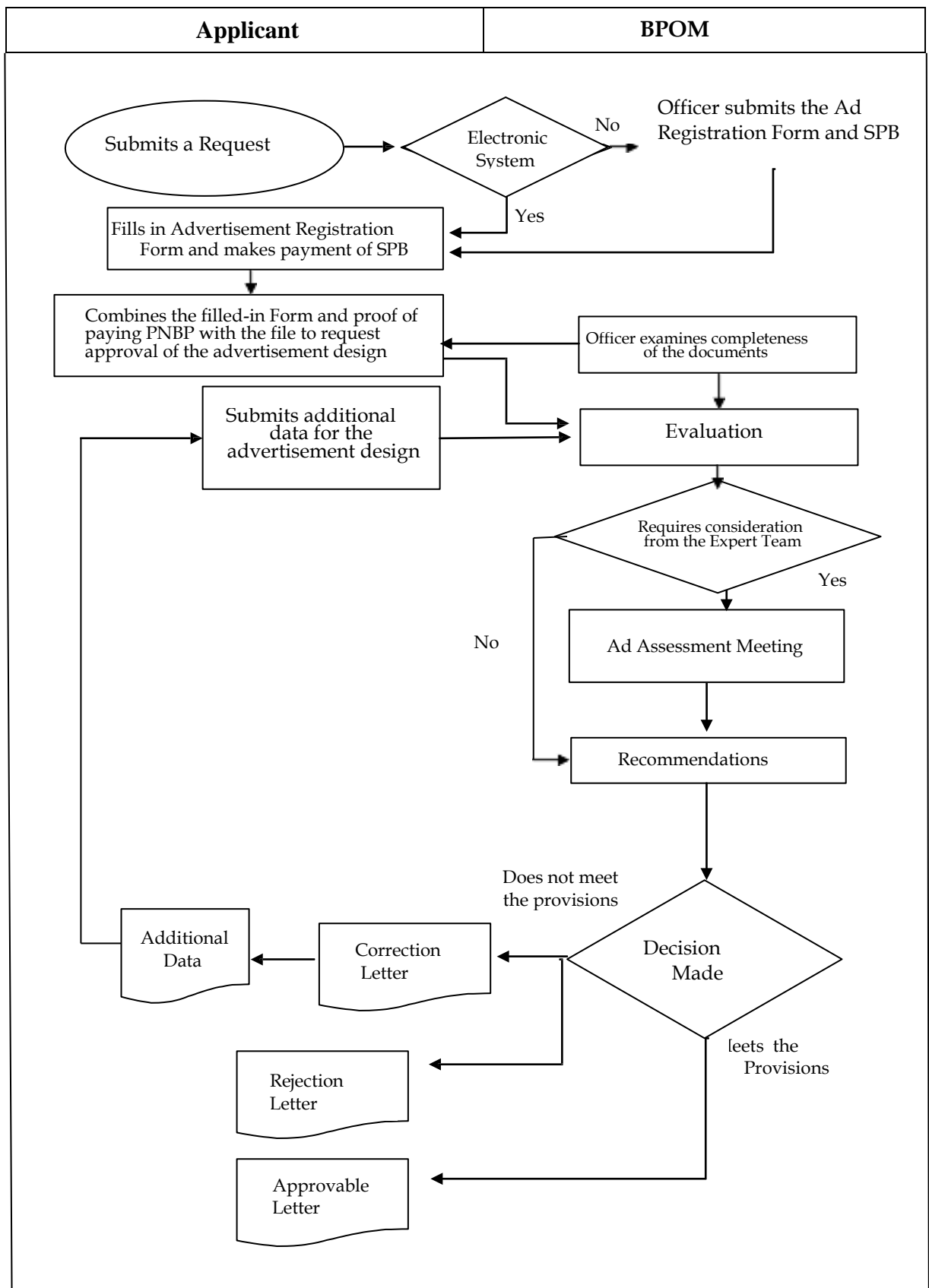
**PART TWO**  
**FRAMEWORK AND STANDARD PROCEDURE**  
**OF SERVICES**

**A. Framework of Procedures**

| <b>No.</b> | <b>Type of Service</b>  | <b>Time of Completion</b> | <b>Cost / Rate</b>   | <b>Service Product</b>  |
|------------|---|---------------------------|--|---|
| 1          | Request for Approval to the Design of the Advertisement for a Drug, Traditional Medicine, Health Supplement, Quasi-drug and Processed Foods | 60 days                   | According to PP Number 32 Year 2017 on Types and Rate on Types of PNPB at BPOM | Letter of Approval to the Design of the Advertisement for a Drug, Traditional Medicine, Health Supplement, Quasi-drug and Processed Foods |

## B. Procedure of Services

Request for Approval to the Design of the Advertisement for a Drug, Traditional Medicine, Health Supplement, Quasi-drug and Processed Foods



### **C. Schedule of Services**

#### 1. Service Counter

Monday–Thursday: 08.30 –16.00WIB Break  
: 12.00 – 13.00WIB  
Friday : 08.30 – 15.30WIB  
Break : 11.30 – 13.30WIB

#### 2. Receive Registrations

Monday–Thursday : 08.30 –15.00WIB  
Break : 12.00 – 13.00WIB  
Friday : 08.30 – 15.00WIB  
Break : 11.30 – 13.30WIB

#### 3. Consultation Service

Monday–Thursday : 08.30 –16.00WIB  
Break : 12.00 – 13.00WIB  
Friday : 08.30 – 15.30WIB  
Break : 11.30 – 13.30WIB

### **D. Service Facilities and Infrastructure**

1. Service Room;
2. Service Desk;
3. Computer;
4. Internet;
5. Charging Station;
6. Waiting Room;
7. Drinking Water;
8. Queue System;
9. Suggestion Box;
10. Lift;
11. Toilet;
12. Parking Lot; and
13. Nursing Room

## **E. Requirements**

### 1. Administrative Documents\*)

- 1) Letter of Request
- 2) Proof of paying PNBPN in accordance with the law

### 2. Technical Documents\*)

- 1) Photocopy of the approvable letter for marketing permit or letter of approval for food registration
- 2) Advertisement designs, 20 copies in the form of:
  - Pictures and writing for the print media
  - storyboard for television
  - script for radio

Each design attached must be clear, with writing in letters that are easy to read (size of the letters should be at least equivalent to *Times New Roman*12)

- 3) Photocopy of data to support certain claims of the advertisement (literature/research journals/survey results), if necessary

Note:

- \*) For requests to obtain approval on advertisements of drugs, traditional medicine, health supplements, and quasi-drugs the administrative documents and technical documents are submitted electronically.

## **F. Place of Services**

Public Service Building

Indonesian Food and Drug Authority

Jl. Percetakan Negara No.23, Central Jakarta 10560

## **SUB-ATTACHMENT I.9**

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY  
NUMBER 27 YEAR 2018  
REGARDING  
PUBLIC SERVICE STANDARDS WITHIN THE SCOPE OF  
THE INDONESIAN FOOD AND DRUG AUTHORITY

**SERVICE STANDARDS FOR  
THE REQUEST TO IMPORT DRUGS, BIOLOGICAL  
PRODUCTS/VACCINE, TRADITIONAL MEDICINES,  
HEALTH SUPPLEMENTS, COSMETICS AND PROCESSED  
FOODS THROUGH A SPECIAL CHANNEL MECHANISM  
OR SPECIAL ACCESS SCHEME (SAS)**

**PART ONE  
INTRODUCTION**

**A. Legal Basis**

1. Law Number 10 Year 1995 on Customs;
2. Law Number 36 Year 2009 on Health;
3. Law Number 18 Year 2012 on Foods;
4. Government Regulation Number 72 Year 1998 on The Safety of Pharmaceutical Preparations and Health Equipment;
5. Government Regulation Number 28 Year 2004 on Safety, Quality and Nutrition of Food;
6. Government Regulation Number 32 Year 2017 on Types and Rate on Types of Non-Tax State Revenue at the Indonesian Food and Drug Authority;
7. Regulation of the Minister of Health Number 1010/Menkes/Per/XI/2008 on Drug Registration as amended by the Regulation of the Minister of Health Number 1120/Menkes/Per/XII/2008;
8. Regulation of the Minister of Health Number 007 Year 2012 on Registration of Traditional Medicines;
9. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 24 Year 2017 on the Criteria and Procedure of Drug Registration;

10. Regulation of the Indonesian Food and Drug Authority Number 30 Year 2017 on The Import of Drugs and Food Into Indonesia;
11. Decision of the Minister of Health Number 1379A/Menkes/SK/XI/2002 regarding Management and Use of Drugs, Health Equipment, and Special Foods;
12. Decision of the Chairperson of the Indonesian Food and Drug Authority Number HK.00.05.3.00914 Year 2002 on Import of Drugs Through a Special Channel;
13. Decision of the Chairperson of the Indonesian Food and Drug Authority of the Republic of Indonesia Number HK.00.05.23.4416 Year 2008 on a Service Level Arrangement within the scope of the Indonesian Food and Drug Authority in the context of *Indonesia National Single Window*;

## **B. Purpose and Objective**

**The purpose of determining service standards** is to become guidelines for the service providers and a reference for the applicants in submitting their request for a Letter of Approval for Import in order to import drugs for research and development of their products, and biological products/vaccines for special purposes and donation, and to import traditional medicines, cosmetics and health supplements as well as processed food products for special use.

**The objective of service standards** is to:

- a. Increase the understanding of the applicant about importing drugs for research and development of products, importing biological products/vaccine for special purposes and for donation, and importing traditional medicines, cosmetics dan health supplements and processed foods for special use, so that they comply with the provisions of the law.
- b. Establish reference/guidelines in the context of issuing an Approvable Letter for Special Use, which is to import drugs, traditional medicines, cosmetics, health supplements and processed foods.

## **C. Definition/General Meaning**

1. **Special Access Scheme Permit**, abbreviated as **SAS Permit**, is a

permit to import drugs, traditional medicines, cosmetics and food supplements into Indonesia through a special channel mechanism for research purposes, including clinical trials, product development, sample registration, assistance/grant/donation, exhibitions and to meet specific needs in certain conditions.

2. **Cosmetics** are a substance or preparation which is meant to be used on the outer part of the human body (epidermis, hair, nails, lips and outer genital organs) or the teeth and mucous membrane of the mouth particularly to clean, make fragrant, alter one's appearance and/or to eliminate body odor or to protect or keep the body in good condition.
3. **Drug** is a manufactured medicine, including biological products, which is a substance or mixture of substances used to influence or to investigate the physiological system or pathological conditions in order to determine a diagnosis, or prevention, healing, recovery, improvement of health, and contraception for humans.
4. **Traditional Medicine** is a substance or mixture of substances such as from plants, animals, minerals, galenic preparations or a combination of such ingredients that have, from generation to generation, been used for medicinal purposes, and can be applied according to the norms of the community.
5. **Orphan Drug** is a drug that is desperately needed for treatment of a rare disease for which the drug has already been proven to be safe and effective.
6. **Processed Foods** are food or drinks processed in certain ways or by certain methods with or without added substances, and includes certain processed foods, food additives, genetically modified foods, and irradiated foods.
7. **Health supplement** is a product meant to fulfill the need for nutrients, to maintain, increase and/or improve the health function; it has nutritious value and/or physiological effect, contains one or more ingredients which can be vitamins, minerals, amino acids and/or non-plant ingredients that can be combined with plant ingredients.
8. **Day** is a work day.

**PART TWO**  
**FRAMEWORK AND STANDARD PROCEDURE**  
**OF SERVICES**

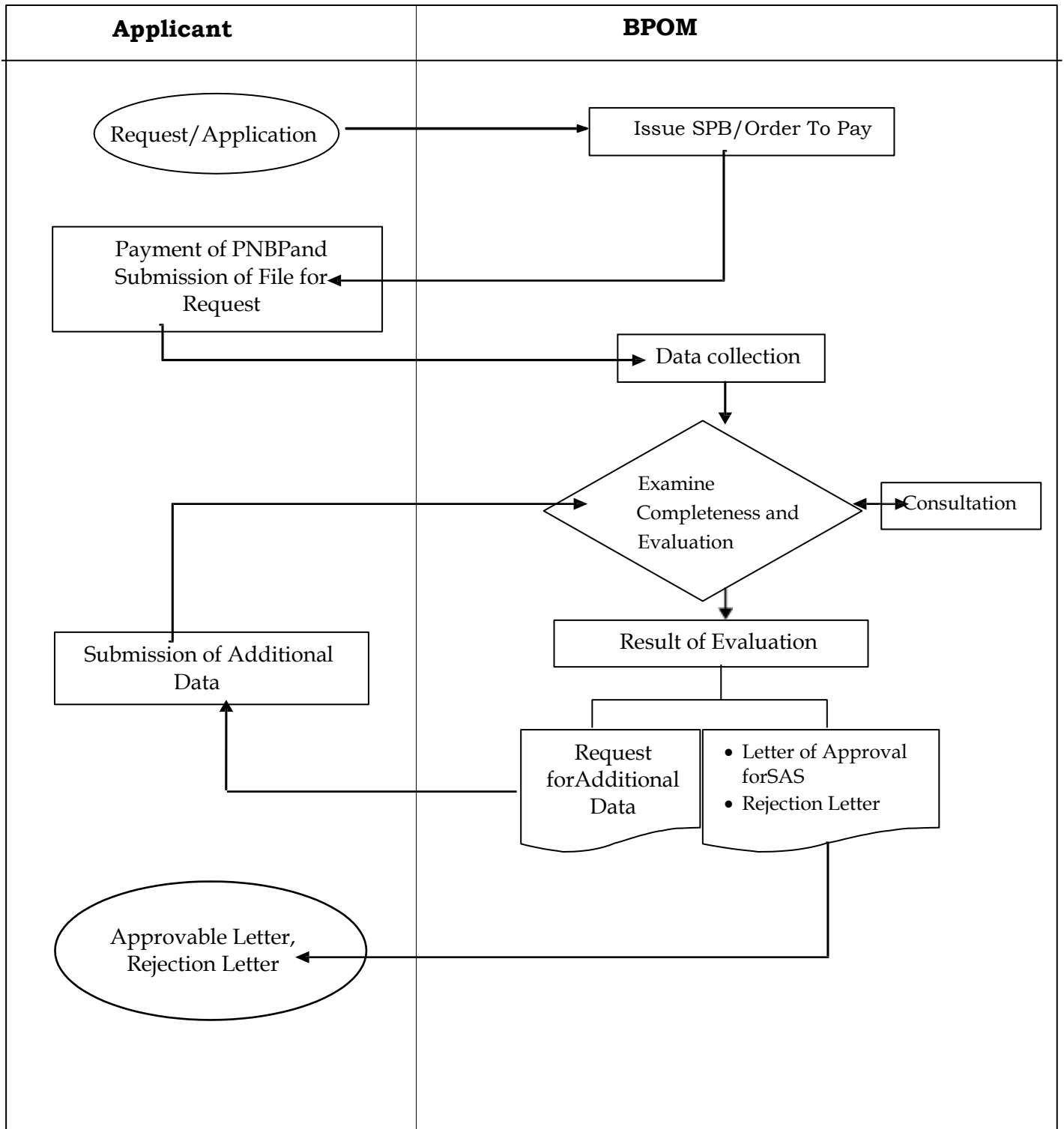
**A. Framework of Procedures**

| <b>No</b> | <b>Type of Service</b>  | <b>Time of Completion</b> | <b>Cost/Rate</b>  | <b>Service Product</b>  |
|-----------|---|---------------------------|---|---|
| 1         | Request to Import Drugs for Research and Development, Biological Products /Vaccine for Special Purposes and for Donation                    | 10 days                   | According to PP Number 32 Year 2017<br><br>On Types and Rate on Types of Non-Tax State Revenue at the Food and Drug Authority | Letter of Approval to Import Drugs Through the Special Channel Mechanism (SAS)  |
| 2         | Request to Import Traditional Medicine, Cosmetics, Health Supplements and Processed Foods for Sample Registration, Research and Exhibitions | 3 days                    |   | Letter of Approval for Importing Traditional Medicines, Cosmetics, Health Supplements and Processed Foods Through Special Channel Mechanism (SAS) |

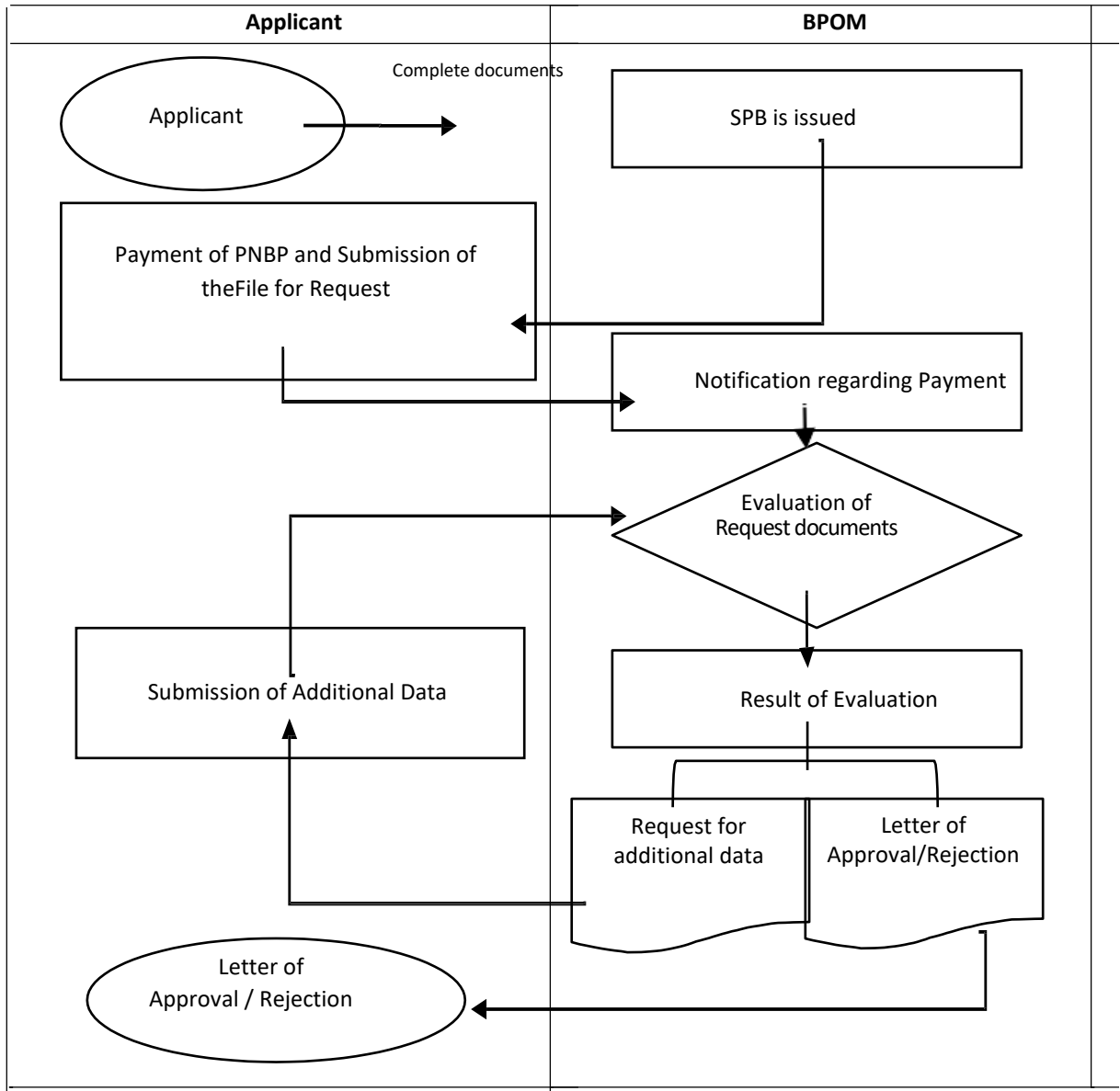
Note \*) :applicable for Processed Foods

**B. Procedure of Services**

**1. Request To Import Drugs for Research and Development, Biological Products/Vaccine For Special Purposes and For Donation Through Special Channel Mechanism/SAS (Special Access Scheme)**



**2. Request to Import Traditional Medicines, Cosmetics, Health Supplements and Processed Foods as Samples for Registration, Research and Exhibition Through Special Channel Mechanism/ SAS(Special Access Scheme)**



### **C. Schedule of Services\***

1. Service Counter

|                 |                |
|-----------------|----------------|
| Monday–Thursday | : 08.30–       |
| 16.00Break      | : 12.00 –13.00 |
| Friday**        | : 08.30 –15.30 |
| Break           | : 11.30 –13.30 |

2. Consultation Service

|                 |                |
|-----------------|----------------|
| Monday–Thursday | : 09.00 –12.00 |
|-----------------|----------------|

\* local time

\*\* service for SAS Drugs is open only until Thursday

\*\*\* receiving SAS Drug Requests according to schedule of the service counter

### **D. Service Facilities and Infrastructure**

1. Service Room
2. Service Desk
3. Computer
4. Waiting Room
5. Wall Board/LCD
6. Suggestion Box
7. Queue System
8. Lift
9. Toilet
10. Parking Lot

### **E. Requirements**

1. Request to Import Drugs for Research and Product Development
  - a. Administrative Documents
    - 1) Letter of Request
    - 2) Statement Letter (with revenue stamp)
    - 3) GMP Certificate of the Producer/Statement letter in replacement of the Producer's GMP Certificate
    - 4) Invoice

- b. Technical Documents
  - 1) Certificate of Analysis/Justification in replacing the CoA
  - 2) Protocol for research or product development and details regarding use of the product
  - 3) Justification regarding the amount needed
  - 4) Details regarding use of the product produced by trial (to be a raw material for drugs)
  - 5) Lot Release Certificate from the authorized laboratory in the country of origin (biological products/vaccine).
  
- 2. Request to Import Biological Products/Vaccine for Private Use or For Donation
  - a. Administrative Documents
    - 1) Letter of request
    - 2) Statement (with revenue stamp)
    - 3) Letter of Program Recommendation (for the program)
    - 4) Letter of recommendation /justification from the doctor responsible (for personal use)
    - 5) GMP Certification of the producer
    - 6) Invoice
    - 7) Informed consent (for personal use)
  
  - b. Technical Documents
    - 1) Information regarding the product (for personal use)
    - 2) Status of marketing of the biological product/vaccine (for personal use)
    - 3) Certificate of Analysis
    - 4) Summary batch protocol of production and testing (from 3 consecutive batches)
    - 5) Certificate of lot release from the authorized laboratory in the country of origin
  
- 3. Request to Import Traditional Medicine, Cosmetics, Health Supplements and Processed Foods as Samples for Registration, Research and Exhibitions
  - a. Administrative Documents
    - 1) Letter of Request from Importer/Producer

- 2) Statement letter from the applicant declaring that such goods will not be sold.
    - 3) Invoice)
    - 4) Packing list
  - b. Technical Documents
    - 1) Certificate of Analysis;
    - 2) Protocol for research or product development for research purposes;
    - 3) Supporting Letter from the Exhibition Organizer for participation in the exhibition;
    - 4) Proposal for the exhibition; and
    - 5) Justification for the amount needed.
  - c. For traditional medicines, health supplements, quasi-drugs and cosmetics, it is prohibited to conduct research with the intention to find out the market.
4. Request to Import Processed Foods for Exhibition, Research and Sample Registration
  - a. Administrative Documents
    - 1) Letter of Request
    - 2) Proof of paying PNBP in accordance with the provisions of the law.
    - 3) Invoice
    - 4) Packing list
    - 5) Bill of Lading (B/L) or Air Way Bill(AWB)
    - 6) Written Statement that the goods will not be sold.
  - b. Technical Documents
    - 1) Certificate of Analysis
    - 2) Product Specification
    - 3) Certificate of Health/Certificate of Free Sale
    - 4) Protocol of research or product development for research purposes
    - 5) Support letter from the exhibition organizer for exhibition purpose
    - 6) Justification of the amount of need
  - c. It is prohibited to carry out such research with the intention of finding out the market for processed foods.
5. Request to Import Processed Foods for Own/Personal Use
  - a. Administrative Documents

- 1) Letter of Request from the applicant or person authorized by the applicant to release the goods intended for own/personal use.
  - 2) Written statement from the applicant that the foods will not be sold.
  - 3) ID Card of the applicant or other legitimate and valid identification (for Indonesian citizens)
  - 4) Passport of the applicant (for foreign citizens)
  - 5) Passport of the applicant and ID Card of the authorized person (for foreign citizens who have authorized an Indonesian citizen).
  - 6) Bill of Lading (B/L) or Air Way Bill (AWB)
- b. Technical Documents
- 1) Letter of request for further action on the samples from the Post Office/Delivery Service/Customs Office to the Agency of Drug and Food Control with sealed test samples for the testing of narcotics and psychotropic drugs
  - 2) Clear packaging / label of the product
  - 3) Letter of Recommendation and supporting data from a doctor.
  - 4) Justification on the amount of need.

**F. Place of Services**

1. Indonesian Food and Drug Authority  
Jl. Percetakan Negara No.23, Jakarta Pusat 10560
2. The appointed Drug and Food Control Agency / Center

## **SUB-ATTACHMENT I.10**

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY  
NUMBER 27 YEAR 2018  
REGARDING  
PUBLIC SERVICE STANDARDS WITHIN THE SCOPE OF  
THE INDONESIAN FOOD AND DRUG AUTHORITY

**SERVICE STANDARDS FOR  
ISSUING A LETTER OF RECOMMENDATION FOR  
APPROVAL TO IMPORT TRADITIONAL MEDICINES,  
HEALTH SUPPLEMENTS AND COSMETICS**

**PART ONE  
INTRODUCTION**

**A. Legal Basis**

1. Law Number 8 Year 1999 on Consumer Protection;
2. Law Number 36 Year 2009 on Health;
3. Government Regulation Number 72 Year 1998 on The Safety of Pharmaceutical Preparations;
4. Presidential Regulation Number 80 Year 2017 on The National Agency of Drug and Food Control;
5. Regulation of the Minister of Health Number 1175/Menkes/Per/VIII/2010 Year 2010 on Cosmetics Production Permit as amended by the Regulation of the Minister of Health Number 63 Year 2013 on Amendment to the Regulation of the Minister of Health Number 1175/Menkes/Per/VIII/2010 Year 2010 on Cosmetics Production Permit;
6. Regulation of the Minister of Health Number 1176/Menkes/Per/VIII/2010 Year 2010 on Cosmetics Notification;
7. Regulation of the Minister of Health Number 006 Year 2012 on Traditional Medicine Industry and Undertakings;
8. Regulation of the Minister of Health Number 007 Year 2012 on Registration of Traditional Medicines;
9. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 14 Year 2014 on The Organization and Working Procedures of the Technical Implementing Unit;

10. Regulation of the Minister of Trade Number 70/MDAG/PER/9/2015 on Importer Identification Number;
11. Regulation of the Minister of Trade Number 87/MDAG/PER/10/2015 on Provisions for the Import of Specific Products;
12. Regulation of the Minister of Trade Number 118/MDAG/PER/12/2015 on Provisions for the Import of Complementary Goods, Goods for Market Testing, and After Sales Service;
13. Regulation of the Minister of Health Number 14 Year 2016 on Recommendations for Approval for the Import of Complementary Goods, Goods for Market Testing, and After Sales Service;
14. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 27 Year 2016 on Methods and Procedure for Recommendations to Obtain Approval for the Import of Drugs, Traditional Medicines, Health Supplement, and/or Cosmetics as Complementary Goods;
15. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 26 Year 2017 on the Organization and Working Procedures of the National Agency of Drug and Food Control;
16. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 30 Year 2017 on Control Over the Import of Drugs and Food Into Indonesia;

## **B. Purpose and Objective**

**The purpose of determining service standards** is to serve as guidelines for the provider of services and as a reference for the applicants in submitting a request for issuance of a Recommendation Letter for Approval to Import Traditional Medicines, Health Supplements and Cosmetics.

**The objective of service standards** is to:

- a. Increase the understanding of the applicants regarding recommendations for obtaining approval to import traditional medicines, health supplements and cosmetics so they can fulfill the provisions of the law; and

- b. Establish a reference/guidelines in the context of issuing recommendation for approval to import traditional medicines, health supplements and cosmetics.

### **C. Definition/General Meaning**

1. **Traditional medicines** is a substance or mixture of substances such as from plants, animals, minerals, galenic preparations or a combination of such ingredients that have, from generation to generation, been used for medicinal purposes, and can be applied according to the norms of the community.
2. **Health supplement** is a product meant to fulfill the need for nutrients, to maintain, increase and/or improve the health function; it has nutritious value and/or physiological effect, contains one or more ingredients which can be vitamins, minerals, amino acids and/or non-plant ingredients that can be combined with plant ingredients.
3. **Cosmetics** are a substance or preparation which is meant to be used on the outer part of the human body (epidermis, hair, nails, lips and outer genital organs) or the teeth and mucous membrane of the mouth particularly to clean, make fragrant, alter one's appearance and/or to eliminate body odor or to protect or keep the body in good condition.
3. **Pharmaceutical Company** is a corporate body that holds a license issued by the Minister of Health to carry out activities in the manufacture of drugs or material for drugs.
4. **Traditional Medicine Industry**, orreferred to as **TMI** is an industry that produces all forms of traditional medicine.
5. **Small Traditional Medicine Company**, which can be abbreviated as **STM**, is an enterprise that can produce all forms of traditional medicines, except tablets and effervescent tablets.
6. **Cosmetics Industry** is an industry that manufactures cosmetics, which holds a business license or industry registration number in accordance with the provisions of the law.
7. **Complementary Goods** are goods imported by a company that holds an Importer Producer Identification Number for the purpose of complementing its line of products, that come from and are produced by a foreign company abroad that has a special relationship with the company owning the Importer Producer

Identification Number.

8. **Special Relationship** is a relationship between the company having the Importer Producer Identification Number and the foreign company abroad, where one party has the capacity to control the other party or has significant influence over the other company according to the applicable accounting standards.
9. **Importer Producer Identification Number** which shall be referred to as **API-P**, is the identification sign as an Importer Producer.
10. **Taxpayer Identification Number (TIN)** is the number given to a taxpayer as a means of identification in tax administration and used to identify the taxpayer in exercising his rights and obligations in taxation.
11. **Business License Number** is the identity of the business player issued and given to the said business player by the OSS (Online Single Submission) Agency after the business player has made a registration.
12. **Applicant** is the traditional medicine industry, small traditional medicine company, cosmetic industry that holds an Importer Producer Identification Number (API- P).
13. **Approval for Import** is approval used as permission to carry out the import of complementary goods, issued by the Minister of Trade.
14. **Day** is a work day.

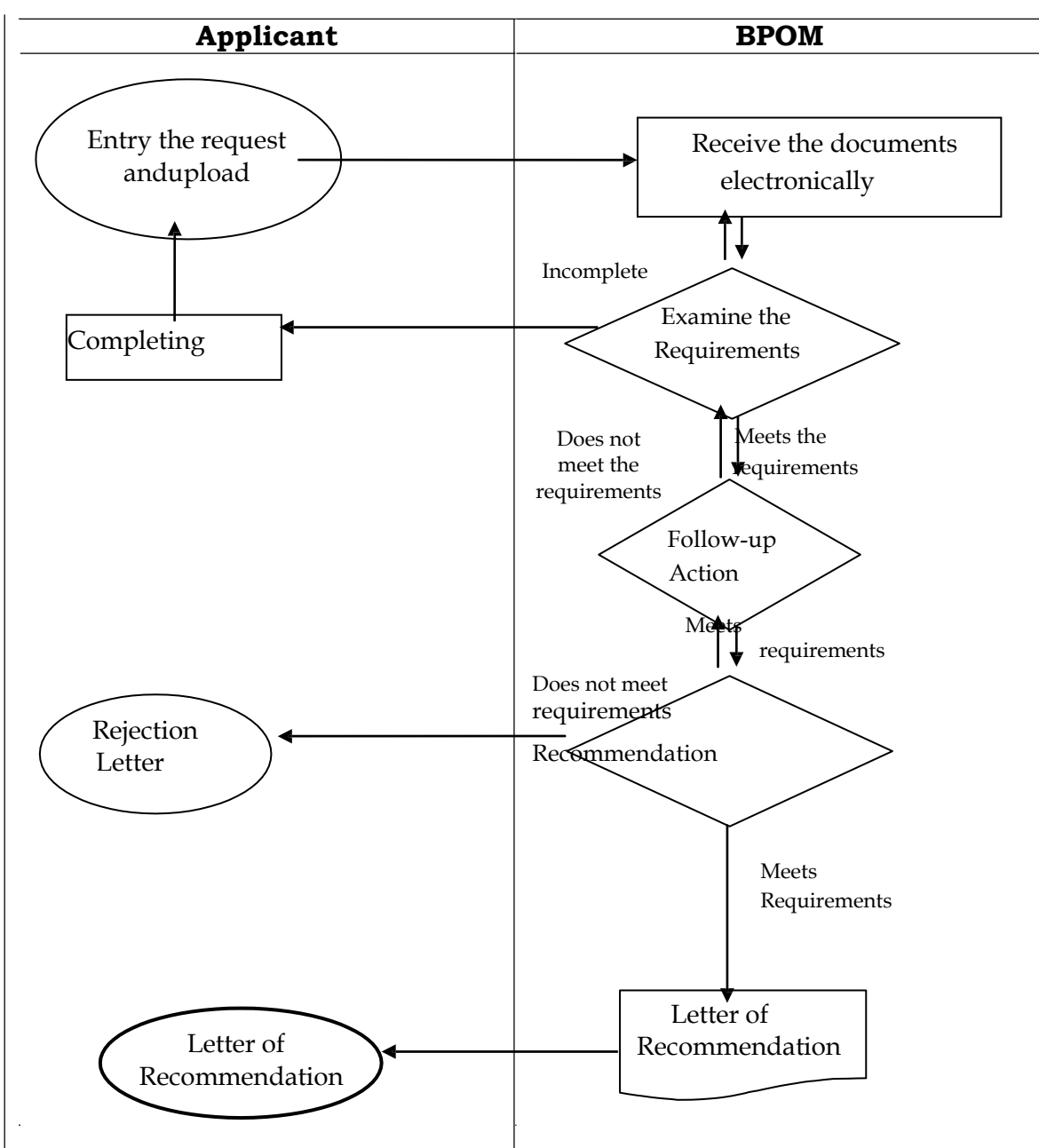
**PART TWO**  
**FRAMEWORK AND STANDARD PROCEDURE**  
**OF SERVICES**

**A. Framework for Procedures**

| <b>No</b> | <b>Type of Service</b>   | <b>Time of Completion</b>                  | <b>Cost/Rate</b> | <b>Service Product</b>   |
|-----------|--|--|------------------|--|
| 1         | Request for Issuance of Recommendation for Approval on the Import of Traditional Medicine, Health Supplements, and Cosmetics | 7 days after the file is declared complete | No cost          | Letter of Recommendation for Approval on the Import of Traditional Medicine, Health Supplements, and Cosmetics |

**B. Procedure of Services**

**1. Request to Issue a Recommendation for Approval to Import Traditional Medicines, Health Supplement and Cosmetics**



### **C. Schedule of Services\***

#### 1. Service Counter

|                 |                |
|-----------------|----------------|
| Monday–Thursday | : 08.30–16.00, |
| Break           | : 12.00 –13.00 |
| Friday          | : 08.30 –15.30 |
| Break           | :11.30 –13.30  |

#### 2. Consultation Service

Monday–Thursday: 09.00 –12.00

\*local time

Note

If the Request File is submitted after 11.30/12.00 then the file will be evaluated on the next day

### **D. Service Facilities and Infrastructure**

1. Service Room;
2. Service Desk;
3. Computer;
4. Waiting Room;
5. Suggestion Box;
6. Tools for Customer Satisfaction Survey
7. Drinking Water
8. Charging Box
9. Queue System;
10. Lift;
11. Toilet;
12. Parking Lot; and
13. Nursing Room.

### **E. Requirements**

#### a. Administrative Documents

- 1) Letter of Request
- 2) List of Traditional Medicine/Health Supplement/Cosmetics

#### b. Technical Documents:

- 1) Pharmaceutical Industry Permit, Traditional Medicine Industry

Permit, Small Traditional Medicine Company Permit,  
orCosmetics Industry Permit

- 2) Importer Producer Identification Number (API-P)\*
- 3) Taxpayer Identification Number (TIN)\*
- 4) Appointment letter of the agency/distributor of the foreign company and cooperative agreement legitimized by a notary
- 5) Approval for Marketing Permit/Registration of the goods to be imported

Note:

\*if already has a NIB, API-P and TIN will not be required

**F. Place of Service**

Public Service Building

Indonesian Food and Drug Authority

Jl. Percetakan Negara No. 23, Central Jakarta 10560

## **SUB-ATTACHMENT I.11**

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY NUMBER  
27 YEAR 2018  
REGARDING  
PUBLIC SERVICE STANDARDS WITHIN THE SCOPE OF  
THE INDONESIAN FOOD AND DRUG AUTHORITY

### **SERVICE STANDARDS FOR REQUEST FOR ISSUANCE OF RECOMMENDATION TO BE RECOGNIZED AS IMPORTER PRODUCER OF HAZARDOUS MATERIAL**

#### **PART ONE INTRODUCTION**

##### **A. Legal Basis**

1. Law Number 8 Year 1999 on Consumer Protection;
2. Law Number 36 Year 2009 on Health;
3. Presidential Regulation Number 80 Year 2017 on The Indonesian Food and Drug Authority;
4. Regulation of the Minister of Health Number 1175/Menkes/Per/VIII/2010 Year 2010 on Cosmetics Production License as amended by the Regulation of the Minister of Health Number 63 Year 2013 on Amendment to the Regulation of the Minister of Health Number 1175/Menkes/Per/VIII/2010 Year 2010 on Cosmetics Production Permit;
5. Regulation of the Minister of Health Number 1176/Menkes/Per/VIII/2010 Year 2010 on Notification of Cosmetics;
6. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 14 Year 2014 on the Organization and Working Procedure of the Technical Implementing Unit;
7. Regulation of the Minister of Trade Number 75/M-DAG/PER/10/2014 on Second Amendment to the Regulation of the Minister of Trade Number 44/M-DAG/PER/9/2009 on Procurement, Distribution, and Control of Hazardous Material;
8. Regulation of the Minister of Trade Number 70/MDAG/PER/9/2015 on Importer Identification Number;

9. Regulation of the Head of the Indonesian Food and Drug Authority Number 26 Year 2017 on the Organization and Working Procedure at the Indonesian Food and Drug Authority;
10. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 30 Year 2017 on Control of the Import of Drugs and Food Into Indonesia;

## **B. Purpose and Objective**

**The purpose of determining service standards** is to have guidelines for the provider of services and a reference for the applicants in submitting their request for recommendation to obtain recognition as IP-B2 (Importer Producer of Hazardous Material).

**The objective of service standards** is to:

- a. Increase the understanding of the applicants regarding the request for recommendation to obtain recognition as IP-B2 (Importer Producer of Hazardous Material) in order to comply with the provisions of the law.
- b. Establish a reference/guidelines in the context of issuing recommendation to obtain recognition as IP-B2 (Importer Producer of Hazardous Material).

## **C. Definition/General Meaning**

1. **Hazardous Material**, which can be referred to as **HM**, is any substance, both chemical and biological, in single form or as a mixture, that is dangerous for health and the environment directly or indirectly, that can be toxic, carcinogenic, teratogenic, mutagenic, corrosive, and irritative.
2. **Company** is any form of individual enterprise or a corporate body owned by an Indonesian citizen and domiciled in the territory of the Republic of Indonesia, as a legal entity or non-legal entity, which conducts activities in the trading of HM.
3. **Producer of Hazardous Material**, or **P-HM** is a company that produces HM in the country and holds an Industry Permit from the authorized institution.
4. **Importer Producer of Hazardous Material**, abbreviated as **IP-HM** is a company that imports HM as raw material or processing

aids for its own production.

5. **Importer Producer Identification Number**, referred to as **API-P**, is the identification sign of the Importer Producer
6. **Business License Number** is the identity of the business player issued by the OSS (Online Single Submission) Agency after the business player has made a registration.
7. **Applicant** is a Cosmetics Industry that holds an API-P.
8. **CAS (Chemical Abstract Service) Number** is an index system or registration system for chemical compounds adopted internationally, thus allowing the identification of any chemical compound specifically.
9. **Day** is a work day.

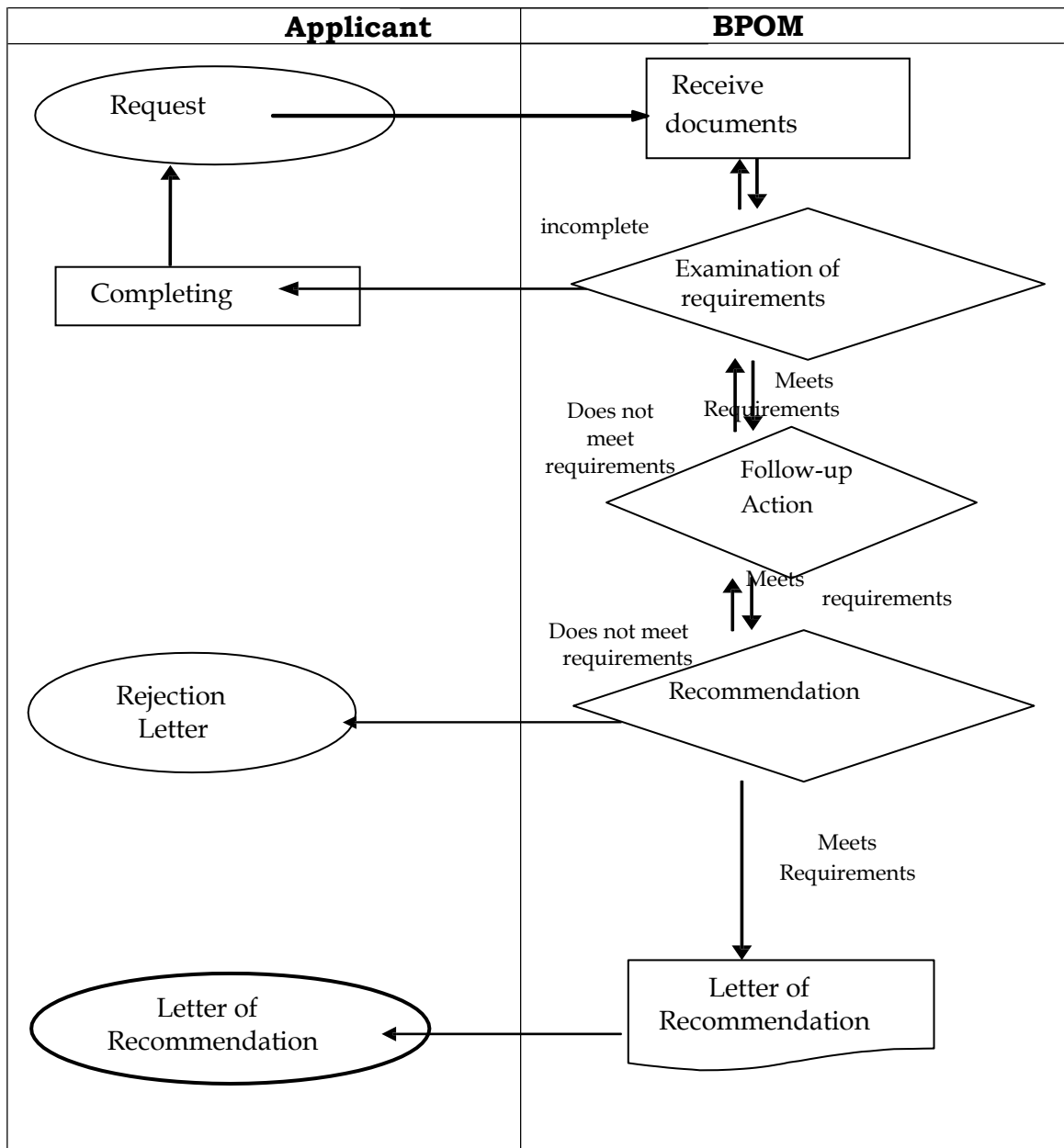
**PART TWO**  
**FRAMEWORK AND STANDARD PROCEDURE**  
**OF SERVICES**

**A. Framework of Procedures**

| <b>No</b> | <b>Type of Service</b>  | <b>Time of Completion</b>                       | <b>Cost / Rate</b> | <b>Service Product</b>  |
|-----------|---|---|--------------------|---|
| 1         | Request for Recommendation to Obtain Recognition as IP-HM (Importer-Producer of Hazardous Material) | 3 days (after the file is declared as Complete) | No cost or charges | Letter of Recommendation to Obtain Recognition as IP-HM (Importer-Producer of Hazardous Material) |

## B. Procedure of Services

### 1. Request for Issuance of Recommendations in Order to Obtain Recognition as IP-HM (Importer Producer of Hazardous Material)



### **C. Schedule of Services\***

#### 1. Service Counter

|                 |                |
|-----------------|----------------|
| Monday–Thursday | : 08.30–16.00  |
| Break           | : 12.00 –13.00 |
| Friday          | : 08.30 –15.30 |
| Break           | : 11.30 –13.30 |

#### 2. Consultation Services

Monday–Thursday: 09.00 –12.00

\*local time

Note:

If the file for request is submitted after 11.30/12.00 then the file will be evaluated on the next day

### **D. Service Facilities and Infrastructure**

1. Service Room;
2. Service Desk;
3. Computer;
4. Waiting Room;
5. Suggestion Box;
6. Tools for Customer Satisfaction Survey;
7. Drinking Water;
8. Charging Box;
9. Queue System;
10. Lift;
11. Toilet;
12. Parking Lot; and
13. Nursing Room.

## **E. Requirements**

The Request for Issuance of Recommendation to Obtain Recognition as IP-HM (Importer Producer Hazardous Material) (soft copy should be sent via online)

### a. Administrative Documents

- 1) Letter of Request
- 2) Industry Business License (IUI)
- 3) Company Registration Certificate (TDP)\*
- 4) Importer Producer Identification Number (API-P)\*
- 5) Taxpayer Identification Number (TIN)\*
- 6) Cosmetic Industry Production Permit

Note:

\*if already has NIB, TDP, API-P and TIN are not required

### b. Technical Documents

- 1) List of hazardous material to be imported, with the CAS Number and HS Code
- 2) Justification of the amount of needed
- 3) Report on realized use of the hazardous material before this

## **F. Place of Services**

1. Public Service Building  
Indonesian Food and Drug Authority  
Jl. Percetakan Negara No. 23, Central Jakarta 10560
2. The appointed Drug and Food Control Agency/Center

## **SUB-ATTACHMENT I.12**

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY  
NUMBER 27 YEAR 2018  
REGARDING  
PUBLIC SERVICE STANDARDS WITHIN THE SCOPE OF  
THE INDONESIAN FOOD AND DRUG AUTHORITY

**SERVICE STANDARDS FOR  
REQUEST OF A REVIEW ON THE SAFETY, QUALITY,  
NUTRITION, BENEFIT AND LABEL OF PROCESSED FOODS**

**PART ONE  
INTRODUCTIONN**

**A. Legal Basis**

1. Law Number 8 Year 1999 on Consumer Protection;
2. Law Number 36 Year 2009 on Health;
3. Law Number 18 Year 2012 on Foods;
4. Government Regulation Number 69 Year 1999 on Labels and Advertisements for Foods;
5. Government Regulation Number 28 Year 2004 on The Safety, Quality and Nutrition of Foods;
6. Regulation of the Minister of Health Number 033 Year 2012 on Food Additives;
7. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.23.07.11.6667 Year 2011 on Control on Food Packaging;
8. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 4 Year 2013 on Maximum Limit of Use of the Food Additive: Carbonizing Agent;
9. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 5 Year 2013 on Maximum Limit of Use of the Food Additive: Humectant;
10. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 6 Year 2013 on Maximum Limit of Use of the Food Additive: Carrier;

11. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 7 Year 2013 on Maximum Limit of Use of the Food Additive: Treated Flour;
12. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 8 Year 2013 on Maximum Limit of Use of the Food Additive: Acidity Regulator;
13. Regulation of the Head of the National Agency of Drug and Food Control Number 9 Year 2013 on Maximum Limit of Use of the Food Additive: Solidifier
14. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 10 Year 2013 on Maximum Limit of Use of the Food Additive: Anti-caking Agents;
15. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 11 Year 2013 on Maximum Limit of Use of the Food Additive: Leavening Agent;
16. Regulation of the Chairperson of the Indonesian Food and Drug Authority: Lining;
17. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 13 Year 2013 on Maximum Limit of Use of the Food Additive: Anti foaming Agent;
18. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 14 Year 2013 on Maximum Limit of Use of the Food Additive: Propellant;
19. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 15 Year 2013 on Maximum Limit of Use of the Food Additive: Thickening Agent;
20. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 16 Year 2013 on Maximum Limit of Use of the Food Additive: Emulsifying Salts;
21. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 17 Year 2013 on Maximum Limit of Use of the Food Additive: Gas for Packing;
22. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 18 Year 2013 on Maximum Limit of Use of the Food Additive: Sequestrant;

23. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 19 Year 2013 on Maximum Limit of Use of the Food Additive: Gel-forming Agent;
24. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 20 Year 2013 on Maximum Limit of Use of the Food Additive: Emulsifier;
25. Regulation of the the Chairperson of the Indonesian Food and Drug Authority Number 21 Year 2013 on Maximum Limit of Use of the Food Additive: Color Retention Agent;
26. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 22 Year 2013 on Maximum Limit of Use of the Food Additive: Foaming Agent;
27. Regulation of the the Chairperson of the Indonesian Food and Drug Authority Number 23 Year 2013 on Maximum Limit of Use of the Food Additive: Flavor Enhancer;
28. Regulation of the the Chairperson of the Indonesian Food and Drug Authority Number 24 Year 2013 on Maximum Limit of Use of the Food Additive: Stabilizer;
29. Regulation of the the Chairperson of the Indonesian Food and Drug Authority Number 25 Year 2013 on Maximum Limit of Use of the Food Additive: Bulking Agent;
30. Regulation the Chairperson of the Indonesian Food and Drug Authority Number 36 Year 2013 on Maximum Limit of Use of the Food Additive: Preservative;
31. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 37 Year 2013 on Maximum Limit of Use of the Food Additive: Food Coloring;
32. Regulation of the the Chairperson of the Indonesian Food and Drug Authority Number 38 Year 2013 on Maximum Limit of Use of the Food Additive: Antioxidant;
33. Regulation of the the Chairperson of the Indonesian Food and Drug Authority Number 4 Year 2014 on Maximum Limit of Use of the Food Additive: Sweetener;
34. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 16 Year 2014 on Amendment to the Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.23.07.11.6667 Year 2001 on Control of Food Packaging;

35. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 10 Year 2016 on Using Processing Aids i.e. Enzymes and Enzyme Adsorbents, in the Processing of Foods;
36. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 13 Year 2016 on Control Over Claims on Labels and in Advertisements of Processed Food;
37. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 21 Year 2016 on Food Categories;
38. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 22 Year 2016 on Terms of Using Flavoring as a Food Additive;
39. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 27 Year 2017 on Registration of Processed Foods;
40. Regulation of the Indonesian Food and Drug Authority Number 1 Year 2018 on Control Over Processed Food for Special Nutritional Needs.

## **B. Purpose and Objective**

**The purpose of determining service standards** is to become available as guidelines for the service providers and as a reference for the applicants in requesting a review and consultation regarding the safety, quality, nutritional content, benefits, and labelling of a processed food.

**The objective of service standards** is to:

- a. Increase the understanding of the stakeholders in the context of requesting a review of the safety, quality, nutritional content, benefits, and labelling of a processed food.
- b. Establishing a reference/guidelines in the context of implementing the request for a review of the safety, quality, nutritional content, benefits, and labelling of a processed food.

## **C. Definition/General Meaning**

1. **Food Additive**, is a substance added to a food to influence the characteristic or physical features of the food.

2. **Processing Aid** is any substance or material, not including equipment, which is often not consumed as food, deliberately used in the processing of a food to meet the goals of a certain technology and which does not leave any residue on the final product or, if it cannot be avoided, the residue and/or its derivative in the final product does not cause a risk to health and does not have any technological function.
3. **Raw Material** is a basic material that can be either fresh or processed, and can be used to produce a food.
4. **Food Packaging** is the material used to contain and/or to wrap food, and may be in direct contact with the food or not.
5. **Food Label** is any information about the food in the form of a picture, writing, combination of both, or in any other form which is included with the food, placed inside or stuck on or is part of the food's wrapping/packaging.
6. **Claim** is any commentary or description that declares, recommends, or indirectly states certain characteristics of a food with regard to its origin, nutritional content, features, production, processing, composition or other quality factors.
7. **Nutritional Claim** is any description that declares, indicates or implies that the food has certain nutritional characteristics, including energy value and protein content, fats and carbohydrates, and vitamin and mineral content.
8. **Health Claim** is any description or commentary that declares, recommends, or implies that there is a relationship between the food or ingredients of the food, with health.
9. **Food Component** is a material or food substance, including nutritional substances, used in the processing of a food and is in the final product even though it has undergone a change.
10. **Processed Foods for Specific Nutritional Need, or PKGK**, is a food which is processed or formulated specially to meet the specific nutritional needs required for the physical conditions of a certain illness/disease.
11. **Food Category** is the grouping of foods according to their type.
12. **Verificator** is the team examining (making verification) of the file that requests a review, established by the Director for Processed Food Standardization.

13. **Online Consultation** is consultation through the subsite *standarpangan.pom.go.id*.
14. **Food** is anything from biological sources, agricultural products, plantation products, forest products, fisheries, livestock, from the waters and water, either processed or not, intended to be food or drinks for human consumption, including food additives, raw materials and other substances used in the process of preparing, processing and/or making food or drinks.
15. **Processed Foods** are food or drinks produced by certain ways or methods, with or without added substances.
16. **Review** is the entire process of examination, analysis and evaluation of the documents in relation to the safety, quality, nutrition and benefits, as well as the label of the food.
17. **Evaluator** is the evaluation team established by the Director of Processed Food Standardization.
18. **Expert Team** is the group of experts formed by the Chairperson of the Indonesian Food and Drug Authority, to carry out reviews and give recommendation on the use of food additives, processing aids, packaging, raw material, food category, food labels, new components, PKGK, and claims about nutrition and health.
19. **e-Standard Application** is a web-based online application prepared by the Directorate of Processed Food Standardization as an electronic system for the process of verifying the files for request and review.
20. **Certification on the Safety of Food Packaging** is a certificate stating that a packaging is safe (not hazardous to human health) for the type of food proposed.
21. **Food Contact Material** is the packaging material that will be in direct contact with the food product.
22. **Food Contact Substance** is any substance intended to be used as a component in the food packaging material that is used in the manufacture, packing, packaging, and storage of food, which in its use is not intended to have any technical effect on the food.

**PART TWO**  
**FRAMEWORK AND STANDARD PROCEDURE**  
**OF SERVICES**

**A. Framework of Procedures**

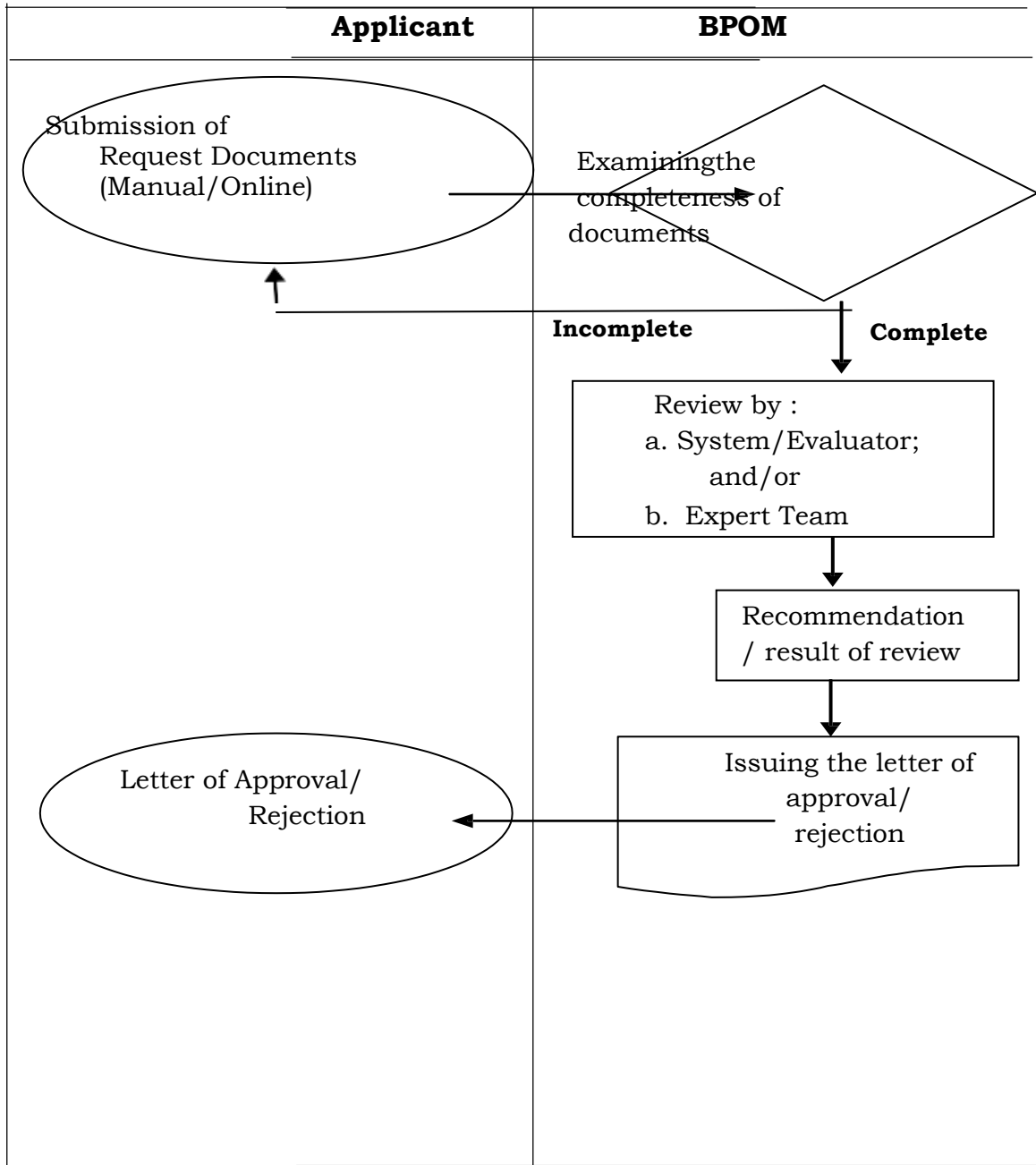
| <b>No.</b> | <b>Type of Service</b>   | <b>Time of Completion</b> | <b>Cost / Rate</b> | <b>Service Product</b>         |
|------------|--|---------------------------|--------------------|--------------------------------|
| 1          | Request for a Review on the Safety, Quality, Nutrition, Benefit and Label of the Processed Food (Manual and Online)      | 85 days                   | No Cost            | Letter of Approval / Rejection |
| 2          | Consultation related to the process of review on the safety, quality, nutrition, benefit and label of the processed food | 1 day                     |                    | Proof of Consultation          |

Note:

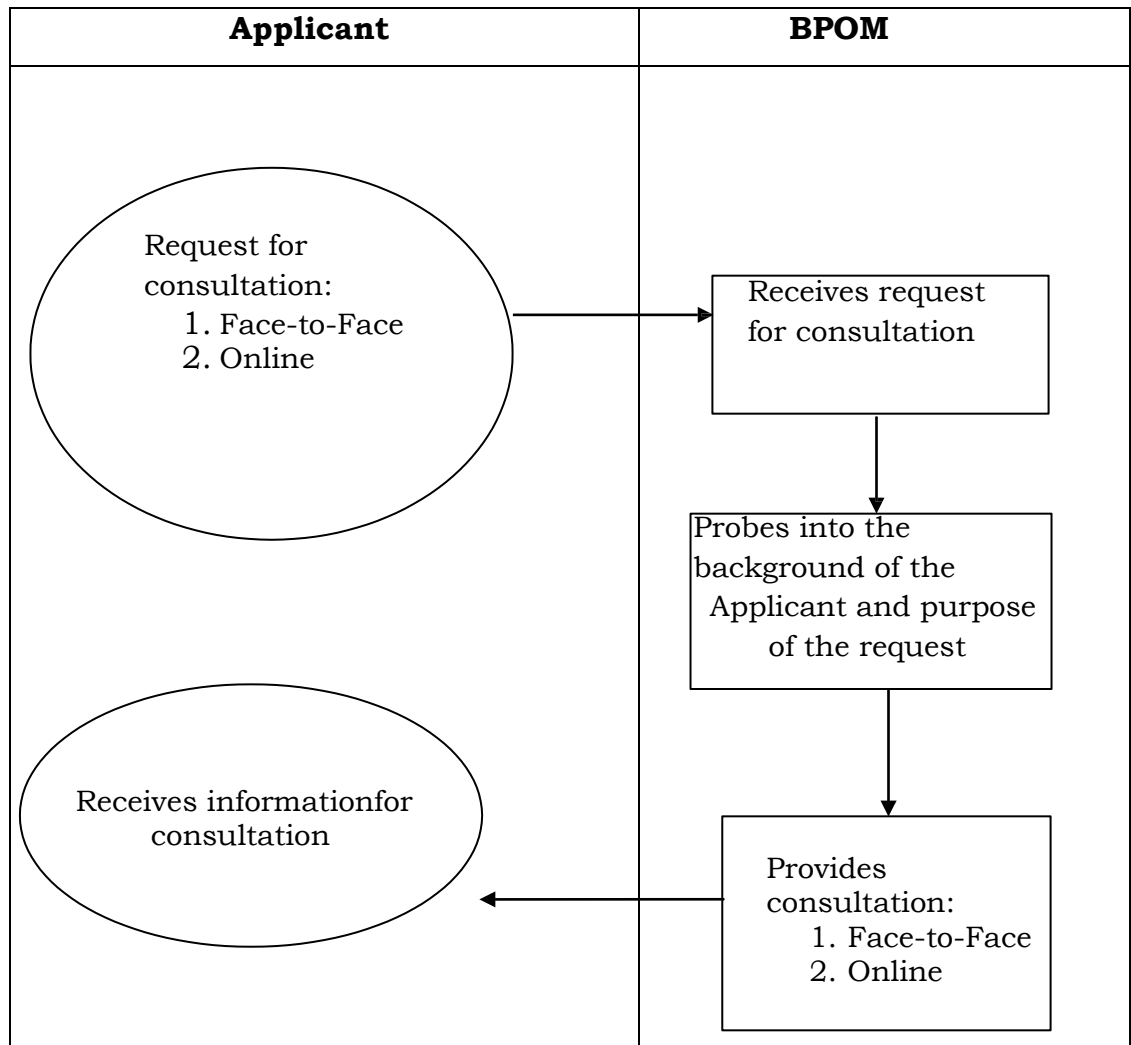
Calculation of the timeline begins as of when the letter of request for a review is declared to be complete in the process of verifying the file, until a response letter is issued.

**B. Procedure of Services**

**1. Request for Review of the Safety, Quality, Nutrition, Benefit and Label of the Processed Food.**



**2. Consultation regarding the Safety, Quality, Nutrition, Benefit, and Label of a Processed Food**



**C. Schedule of Services**

**1. Registration of Service:**

Day : Monday –Thursday  
Time : 09.00 – 12.00WIB

**2. Consultation Service (face-to-face and online)**

Day : Monday –Thursday  
Time : 09.00 – 15.30WIB  
Break : 12.00 – 13.00WIB

**3. Serving the Request for Review of the Safety, Quality, Nutrition, Benefit, and Label of a Processed Food (manual)**

Day : Monday –Thursday  
Time : 09.00 – 15.30WIB  
Break : 12.00 – 13.00WIB

**4. Serving the Request for Review of The Safety, Quality, Nutrition, Benefit and Label of the Processed Food (online)**

Day : Monday –Thursday

Time : 09.00 – 12.00WIB

**D. Service Facilities and Infrastructure**

1. e-Standard Application for Foods;
2. Form for requesting a review;
3. Form for consultation;
4. e-Form for Assessment of Customer Satisfaction;
5. Service Room;
6. Service Desk;
7. Computer;
8. Internet;
9. Charging station;
10. Waiting Room;
11. Drinking Water;
12. Queue System;
13. Suggestion Box;
14. Lift;
15. Toilet; and
16. Parking Lot.

**E. Requirements**

1. Administrative Documents
  - a. Request for review of the safety, quality, nutrition, benefit and label of a Processed Food.
  - b. Data on the applicant
2. Technical Documents
  - a. Food Additive
    - 1) Name of chemical, composition, specifications or quality of the substance, physical and chemical characteristics, chemical formula and structural formula;
    - 2) Method of production, method of analysis suitable for determining the level and purity of a food additive;

- 3) Function/purpose of using, recommendation and instructions for use, physiological effect, techniques and ways to use food additives and types of food and the maximum amount that can be used in foods;
- 4) Testing the safety of a food additive and the maximum limit of the food additive that can be used in the food product

b. Processing Aids

- 1) General data on the processing aids (chemical name, international code, chemical formula, composition of processing aids, specifications of quality, how to make a processing aid).
- 2) Application of processing aids in food (composition of Food product, the amount of processing aids used in the process of food production, function/purpose of using processing aids, how the processing aid works so that the desired effect in the food product can be achieved, result of analyzing the processing aids in a food product, flow of production of food products, how to eliminate the existence of the processing aid in the end product).

c. Food Categories and Food Labels

- 1) Data on the product and its designated use
- 2) Ingredients used
- 3) Type of request for review (Category of the Food/Label\*)
- 4) Description of the Request submitted
- 5) Proof of receiving complete documents

\*) choose one

d. Raw Material

- 1) Name of the raw material
- 2) Quantity of the raw material
- 3) Composition of the raw material
- 4) Flow of the production process of the raw material
- 5) Specifications of quality of the raw material
- 6) Result of analysis (*Certificate of Analysis/CoA*)
- 7) Method of analyzing level of active ingredients

- 8) Acute toxicity
- 9) Chronic toxicity
- 10) Carcinogenic
- 11) Mutagenic
- 12) Toxicity against reproduction
- 13) Irritation
- 14) History of being used as a food
- 15) Type of food
- 16) Composition of the food product
- 17) Process of production of the processed food

e. Nutritional Claim / Health Claim / Nutritional Substance/ Non Nutritional Substance

- 1) Product specifications and data on the product.
- 2) Name of component that was added, with/without its chemical structure
- 3) Purpose of the addition
- 4) Claim put forth
- 5) Quantity of the food component consumed in a day
- 6) Process of production
- 7) Method and result of analysis on the nutritional substances and other components in the end product
- 8) History of its use as a food

f. Processed Foods for Special Nutritional Needs (PKGK)

- 1) General information on the product
- 2) Specific Information
  - a) Composition of the product
  - b) Targeted customers
  - c) Name of nutritional substance/non-nutritional substance that was added, with/without its chemical structure (If a new nutritional substance/non nutritional substance was added)
  - d) Purpose of adding nutritional/non nutritional substance
  - e) Quantity of nutritional/non nutritional substance added
  - f) Quantity of processed food/nutritional/non nutritional substance consumed in a day

- g) Label information submitted (complete with sample of label)
- h) Production process of the processed food/nutritional/non nutritional substance
- i) History of use as a food (especially the use of herbs)
- j) Method and result of analyzing processed food/nutritional/non nutritional substance

g. Food Packaging

- 1) Specifications of the food packaging
- 2) Scientific reference on reviews of safety and the status of regulations in other countries (at least 3)
- 3) Result of a migration analysis from a government laboratory or an accredited laboratory
- 4) Certificate declaring the packaging is already selling in that country (*Free Sale*), for the packaging of imported food
- 5) Sample packaging/material/food contact substance (if needed)
- 6) Sample of the product

3. Supporting reference, namely:

- a. Food Additive
  - 1) Regulations of other countries, at least 5 countries or international organizations
  - 2) Supporting data on reviews of safety
- b. Food Packaging
 

Status of regulations in various countries
- c. Processing Aids, Raw Material, Nutritional Substance, and Non Nutritional Substance
  - 1) Proof and or related scientific reference (at least 1)
  - 2) Regulations of other countries (at least 3)
  - 3) Supporting data on reviews of safety (result of toxicity testing, international status of safety, such as: JECFA, JEMNU, GRAS)
  - 4) Supporting data on the benefits of processed foods/ new nutritional/non nutritional substances (the results of

- published research, textbook)
- d. Label, Claims
    - 1) Proof and or related scientific reference (at least 3)
    - 2) Sample of product label design, design for stating claims on the label
  - e. Category of Foods
    - Proof and/or related scientific reference (at least 3)

**F. Place of Services**

Public Services Building

the Chairperson of the Indonesian Food and Drug Authority

Jl. Percetakan Negara No. 23, Central Jakarta 10560

## **SUB-ATTACHMENT I.13**

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY  
NUMBER 27 YEAR 2018  
REGARDING  
PUBLIC SERVICE STANDARDS WITHIN THE SCOPE OF  
THE NATIONAL AGENCY OF DRUG AND FOOD CONTROL

**SERVICE STANDARDS FOR  
REVIEW OF THE SAFETY OF GENETICALLY  
MODIFIED FOOD PRODUCTS**

**PART ONE  
INTRODUCTION**

**A. Legal Basis**

1. Law Number 8 Year 1999 on Consumer Protection;
2. Law Number 21 Year 2004 on Ratification of the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*;
3. Law Number 36 Year 2009 on Health;
4. Law Number 18 Year 2012 on Foods;
5. Government Regulation Number 69 Year 1999 on Labels and Advertisements for Food;
6. Government Regulation Number 28 Year 2004 on The Safety, Quality, and Nutrition of Foods;
7. Government Regulation Number 21 Year 2005 on Biological Safety of Genetically Modified Products;
8. Presidential Regulation Number 39 Year 2010 on The Committee for Biological Safety of Genetically Modified Products (KKH PRG), amended by the Presidential Regulation Number 53 Year 2014.

**B. Purpose and Objective**

**The purpose of determining service standards** is to become guidelines for the service providers and as reference for the applicants in requesting service in the form of reviews and consultation regarding the safety of Genetically Modified Food Products.

**The objective of service standards** is to:

- a. Increase the understanding of the stakeholders in the context of requesting a review of the safety of genetically modified foods.
- b. Establish a reference/guidelines in the framework of providing service, i.e. the review of the safety of genetically modified food products.

### **C. Definition/General Meaning**

#### **1. Clearing Center for Biological Safety of Genetically Modified Products**

**(Balai Kliring Keamanan Hayati Produk Rekayasa Genetik)**, which here in shall be referred to as **BKKH** is a tool of the Committee for Biological Safety (*Komisi Keamanan Hayati/ KKH*) that functions as a means of communication between KKH and the stakeholders.

#### **2. Safety of Genetically Modified Foods (GMF)** is a condition and effort needed to prevent the possibility of any arising impact that is detrimental and hazardous to human health, as a result of the production process, preparation, storage, marketing and utilization of genetically modified foods.

#### **3. Committee for Biological Safety of Genetically Modified Foods**, here in referred to as **KKH PRG**, isa committee whose task is to give recommendations to the authorized Minister and the Heads of Non Ministerial Government Agencies who are authorized to formulate and set the policies and issue certificates regarding the biological safety of genetically modified food products.

#### **4. Food** is anything that comes from biological sources, agricultural products, from plantations, forests, fisheries, livestock, waters and water, either processed or not processed, and meant to be food or drinks for human consumption, including food additives, raw material for foods, and other substances used in the process of preparing, processing, and/or making food and drinks.

#### **5. Genetically Modified Foods** is food which is produced or which uses raw material, food additives, and/or other substances that are produced by the process of genetic modification.

#### **6. Announcement** is the delivery of information to the public about the results of evaluation and technical review about biological safety of genetically modified organisms through official news

released by the KKH and announcement boards or mass media before a recommendation is given regarding biological safety of Genetically Modified Products by KKH.

7. **Review** is the entire process of examining documents and testing the Genetically Modified Food Products, as well as the related social-economic factors.
8. **Genetically Modified Food (GMF) or modified organism**, is a living organism, its parts and/or the result of processing that has a new genetic structure as the outcome of applying modern biotechnology.
9. **Technical Team for Biological Safety of Genetically Modified Food (TTKH)** is a team assigned to assist KKH in making an evaluation and technical review of the biological safety and feasibility in utilizing GMF.

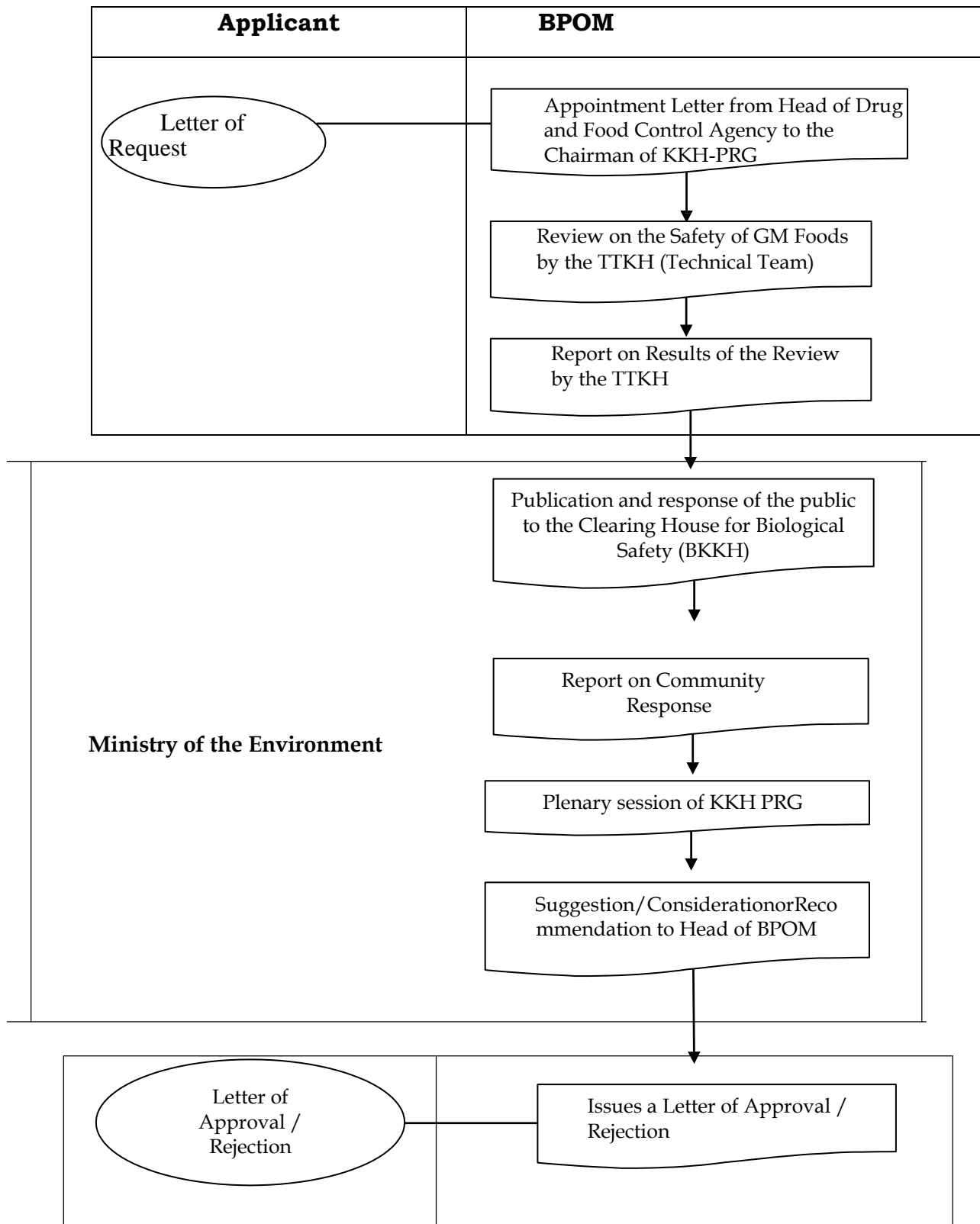
**PART TWO**  
**FRAMEWORK AND STANDARD PROCEDURE**  
**OF SERVICES**

**A. Framework of Procedures**

| <b>No.</b> | <b>Type of Service</b>  | <b>Time of Completion</b> | <b>Cost/Rate</b>   | <b>Service Product</b>   |
|------------|---|---------------------------|--|--|
| 1          | Request for a Review of the Safety of GMF                               | 56 calendar days          | According to PP Number 39Year 2010 onthe Committee for Biological Safety of Genetically Modified Food (GMF) (Article 17 Paragraph (2): The financing needed to conduct a review of the biological safety of GMF will be burdened to the applicant who requests the review of the biological safety of GMF. | Letter of Approval / Rejection of Safety of the GMF Products . |
| 2          | Consultation related to process of reviewing the safety of GMF products | 1 day.                    | No cost.   | Consultation Results.  |

**B. Procedure of Services**

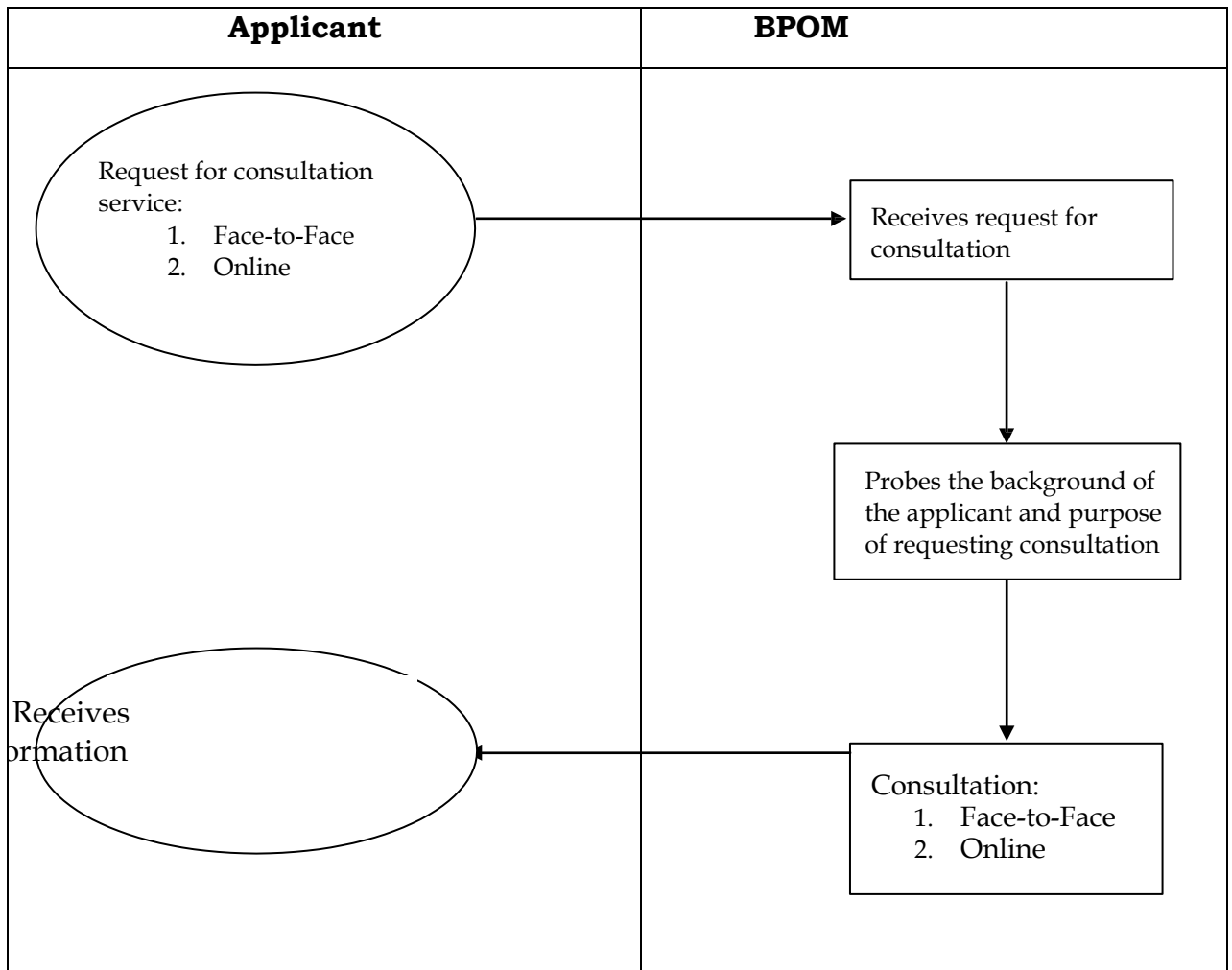
**1. Request for Review of the Safety of GM Foods**



Note:

Calculation of the timeline begins as of receiving the appointment letter from the Vice Chairman of KKH PRG for Food Safety until a letter of request for additional data is issued to the applicant or a letter of report on review results is issued to the Vice Chairman of KKH PRG for Food Safety.

## 2. Consultation Related to Process of Reviewing Safety of GM Foods



### C. Schedule of Services

#### 1. Registration of Services:

Day : Monday –Thursday

Time : 09.00 – 12.00WIB

#### 2. Consultation Service (face-to-face and online)

Day : Monday –Thursday

Time : 09.00 – 15.30WIB

Break : 12.00 – 13.00WIB

#### 3. Counter for Requests to Review Safety of GM Foods

Day : Monday –Thursday

Time : 09.00 – 15.30WIB

Break : 12.00 – 13.00WIB

#### **D. Service Facilities and Infrastructure**

1. Form to request review;
2. Form for consultation;
3. e-Form to Assess Customer Satisfaction;
4. Service Room;
5. Service Desk;
6. Computer;
7. Internet;
8. Charging station;
9. Waiting Room;
10. Drinking Water;
11. Queue System;
12. Suggestion Box;
13. Lift;
14. Toilet; and
15. Parking Lot.

#### **E. Requirements**

##### 1. Administrative Documents

- a. Request for review of the Safety of GM Foods
- b. Data on applicant
- c. Data on GM foods: genetic information (general description of GM foods, description of the host and its use as food, description of the gen sources, description of the method of genetic transformation, and characterizing genetic modification); information on safety of foods (substantial understanding, change in composition of the food, allergenicity, toxicity, and other considerations);

##### 2. Technical Documents

Applicant fills in a form to request review of the safety of genetically modified food products and attaches the required data and documents.

#### **F. Place of Services**

Public Service Building

the Indonesian Food and Drug Authority

Jl. Percetakan Negara No. 23, Central Jakarta 10560

## **SUB-ATTACHMENT I.14**

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY  
NUMBER 27 YEAR 2018  
REGARDING  
PUBLIC SERVICE STANDARDS IN THE SCOPE OF  
THE INDONESIAN FOOD AND DRUG AUTHORITY

**SERVICE STANDARDS FOR  
REQUEST OF APPROVAL TO CONDUCT CLINICAL TESTS  
ON PROCESSED FOODS**

**PART ONE  
INTRODUCTION**

**A. Legal Basis**

1. LawNumber 8 Year 1999 onConsumer Protection;
2. LawNumber 36 Year 2009 onHealth;
3. LawNumber 18 Year 2012 onFoods;
4. Government RegulationNumber 69 Year 1999 on Labels andAdvertisements for Food;
5. Government RegulationNumber 28 Year 2004 onthe Safety, Quality, and Nutrition of Foods;
6. Government RegulationNumber 32 Year 2017 onTypes and Rate on Types of Non-Tax State Revenue at the Indonesian Food and Drug Authority;
7. Regulation of the Head of the Indonesian Food and Drug Authority Number 21 Year 2015 on Procedure of the Approval for Clinical Trial/Test;
8. Regulationof the Chairperson of the Indonesian Food and Drug Authority Number 13 Year 2016 onControl Over Claims on the Labels and Advertisement of Processed Foods;
9. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 1 Year 2018 on Control on Processed Foods for Special Nutritional Needs.

**B. Purpose and Objective**

**The purpose of determining service standards** is to become guidelines for the providers of service and a reference for the applicants in

obtaining evaluation of documents and consultation related to the request for Approval to Conduct Clinical Trials on Processed Foods.

**The objective of service standards** is to:

- a. Increase the understanding of stakeholders in the context of requesting Approval to Conduct Clinical Trials/Tests on Processed Foods.
- b. Establish a reference/guidelines in the context of implementing the request for Approval to Conduct Clinical Trials on Processed Foods.

### **C. Definition/General Meaning**

1. **Clinical Trial** is a research activity that involves humans as the subject of research with intervention of the trial/test product, in order to find or to ensure a clinical effect, pharmacological and/or other pharmacodynamic effect, and/or to identify any unwanted reactions, and/or to study the absorption, distribution, metabolism and excretion in order to make sure of the safety and/or effectiveness of the product being researched.
2. **Food** is anything that comes from biological sources, agricultural products, from plantations, forests, fisheries, livestock, waters and water, which is either processed or not processed, meant to be food or drinks for human consumption, including food additives, raw materials for food, and other substances used in the process of preparing, processing, and or making food or drinks.
3. **Processed Food** is food and drink made by certain ways and methods of processing with or without using food additives.
4. **Approval to Conduct Clinical Trial/Test** is the approval to carry out clinical testing, issued by the Head of Agency.
5. **Team for Evaluation of Clinical Trial Documents** is the evaluation team established by the Head of the Agency to make an evaluation of the documents submitted for the request.
6. **Ethics Commission** is an independent institution consisting of medical/scientific professionals and non-medical/non-scientific members in the field of clinical testing, who are responsible for the protection, rights, safety and welfare of the Test Subject.
7. **Contract Research Organization**, which shall be referred to as ORK, is an individual or an organization (commercial or other) who is

contracted by a sponsor to perform one or more of the tasks and function of the sponsor in the Clinical Test.

8. **Test Product** is the processed food that will be used in the clinical test, as a product to be tested or as the product that will be used as a comparator.
9. **Protocol for Clinical Trial/Testing** is a complete and detailed document that describes, among others, the organization of a clinical test, background, objective, design, methodology, and statistical considerations.
10. Approval After Explanation or **Informed Consent**, is a process to get approval from the subject; after having received explanation about all relevant aspects of the clinical trial/testing, the subject voluntarily without any form of coercion declares his/her willingness to participate in a clinical trial/test.

**PART TWO**  
**FRAMEWORK AND STANDARD PROCEDURE**  
**OF SERVICES**

**A. Framework of Procedures**

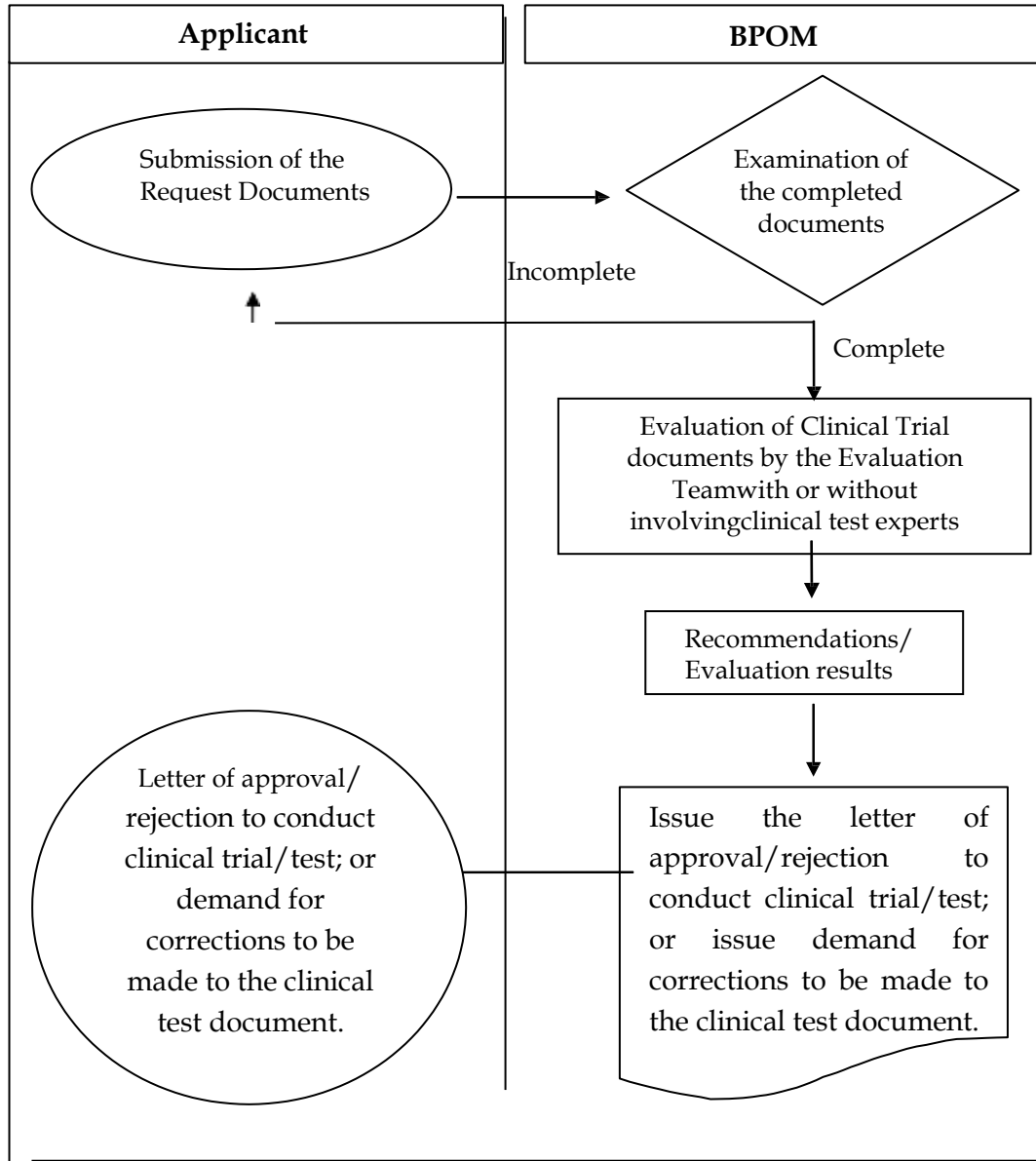
| <b>No.</b> | <b>Type of Service</b>  | <b>Time of Completion</b> | <b>Cost / Rate</b>  | <b>Service Product</b>  |
|------------|---|---------------------------|---|---|
| 1          | Request for Approval to Conduct Clinical Test on a Processed Food                     | 20 days                   | According to Government Regulation Number 32 Year 2017 on PN BP (Non Tax State Revenue) | Letter of Approval / Rejection for conducting clinical test; or request for correction to the clinical test documents |
| 2          | Consultation related to the process of Approving a Clinical Trial for Processed Foods | 1 day                     | No cost / free of charge  | Proof of consultation   |

Note:

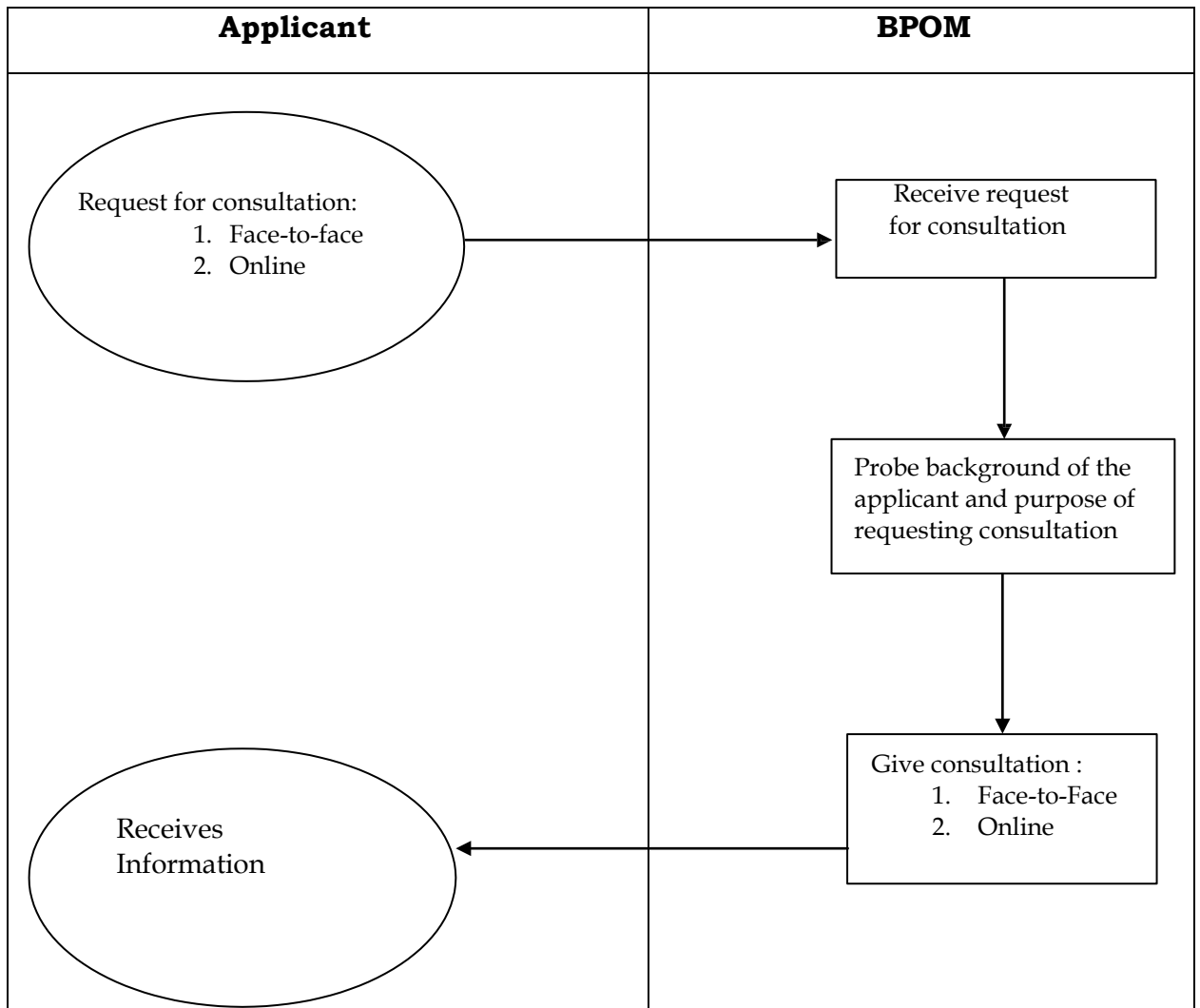
Calculation of the timeline begins as of the day the letter of request for approval is declared complete and sufficiently detailed in the process of verifying the file, until the response letter is issued.

## Procedure of Services

### 1. Request for Approval to Conduct Clinical Trial/Test on Processed Food



## 2. Consultation Related to Process of Approving Clinical Tests on Processed Foods



### B. Schedule of Services

#### 1. Registration of Services:

Day : Monday -Thursday

Time : 09.00 – 12.00WIB

#### 2. Consultation Service (face-to-face andonline)

Day : Monday -Thursday

Time : 09.00 – 15.30WIB

Break : 12.00 – 13.00WIB

#### 3. Servicing the Requests for Approval to Conduct Clinical Test on Processed Food

Day : Monday -Thursday

Time : 09.00 – 15.30WIB

Break : 12.00 – 13.00WIB

**C. Service Facilities and Infrastructure**

1. Form to request Approval for Clinical Trial/Test;
2. Form for consultation;
3. e-Form for Assessment of Customer Satisfaction;
4. Service Room;
5. Service Desk;
6. Computer;
7. Internet;
8. ChargingStation;
9. Waiting Room;
10. Drinking Water;
11. Queue System;
12. Suggestion Box;
13. Lift;
14. Toilet;and
15. Parking Lot.

**D. Requirements**

1. Administrative Documents
  - a. Letter of Request for Approval to Conduct Clinical Test on Processed Food.
  - b. Form to request approval for clinical test on processed food.
2. Technical Documents
  - a. Protocol for clinical trial/test
  - b. Approval After Explanation (Informed Consent)
  - c. Investigator brochure
  - d. Approval from the Ethics Committee (if any)
  - e. Data of previous phase (non clinical data, data of phase 1 or other scientific data) (if needed)
  - f. Information on the product used for the clinical trial
  - g. Information on the product to be imported in connection with the clinical trials (If necessary)
  - h. GMP Certificate

### 3. Supporting Documents

- a. Certificate of *Good Clinical Practice* (GCP) of the investigator
- b. ORK contract document ORK (if using ORK)
- c. Insurance (if any)
- d. Laboratory certificate
- e. Composition of Investigation Team
- f. Other related data

#### **E. Place of Services**

Public Service Building

the Indonesian Food and Drug Authority

Jl. Percetakan Negara No. 23, Central Jakarta 10560

## **SUB-ATTACHMENT I.15**

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY  
NUMBER 27 YEAR 2018  
REGARDING  
PUBLIC SERVICE STANDARDS IN THE SCOPE OF  
THE INDONESIAN FOOD AND DRUG AUTHORITY

**SERVICE STANDARDS FOR A  
REQUEST TO TEST DRUGS AND FOOD AND  
CALIBRATION OF LABORATORY EQUIPMENT**

**PART ONE  
INTRODUCTION**

**A. Legal Basis**

1. Government Regulation Number 32 Year 2017 on Types and Rateon Types of Non-Tax State Revenue at the Indonesian Food and Drug Authority;
2. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.00.06.1.52.4011 Year 2009 on Determining the Maximum Limit for Contamination by Microbes and Chemicals in Food;
3. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.23.07.11.6662 Year 2011 on Terms for Contamination by Microbes and Heavy Metals in Cosmetics as amended by the Head of the Indonesian Food and Drug Authority Number 17 Year 2014;
4. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 23 Year 2017 on Maximum Limit of Contamination by Heavy Metals in Processed Foods;
5. Regulation of the Indonesian Food and Drug Authority Number 30 Year 2017 on Control on Import of Drugs and Food;
6. Decision of the Chairperson of the Indonesian Food and Drug Authority Number HK.00.06.331.3.1655 Year 2009 on Establishing the Procedure to Release a Batch/Lot of Vaccines for Humans;
7. Ministry of Health of RI, 1995, Pharmacopoeia Indonesia IV and Supplement of Pharmacopoeia Indonesia;

8. SNI ISO/IEC 17025:2008:Requirements for Standard Competence of the Test Laboratory and Calibration Laboratory;
9. Manual on Quality SNI ISO/IEC 17025:2008 approved by the Laboratory Top Manager within the scope of BPOM.

## **B. Purpose and Objective**

**The purpose of determining service standards** is to become the guidelines for providing laboratory services within the scope of the BPOM and as reference for the applicants in submitting a request to test drugs and food and a request to calibrate laboratory equipment.

**The objective of service standards** is to:

- a. Increase the understanding of the applicants in submitting their request for approval to test drugs and food, and to calibrate laboratory equipment.
- b. Provide service in testing drugs and food and performing calibration of laboratory equipment in accordance with the prescribed quality standards.

## **C. Definition/General Meaning**

1. **Amendment** to the Test Certificate/Report will be issued if there are some test parameters not yet reported or there is an error in the test results that could affect or change the conclusion.
2. **Calibration** is a series of activities to determine the connection between the score indicated by the measuring instrument or system of measure or the measuring material or reference material (under certain conditions) and the score realized by the standards.
3. **Calibration In Site** is calibration performed at the location of the customer, at a temporary facility or in a mobile facility.
4. **Calibration Ex Site** is calibration which is carried out at PPPOMN.
5. **Calibration Laboratory** is a laboratory which has the task of performing calibration to ensure accuracy of the measuring instrument or the tool used in the test which requires a specific degree of accuracy that can affect the validity of the test results.
6. **Test Report** is a collection of information that provides confirmation on one or more measuring scores, or information about the material tested, using equipment or not using equipment.

7. **Test Laboratory within the scope of BPOM (PPPOMN and Drug and Food Control Agency/Center)** is a laboratory that performs examination, testing and assessment of the quality of a drug, of narcotics, psychotropic drugs, precursors, and addictive substances, health equipment, household health supplies, biological products, traditional medicines, cosmetics, health supplements, food and water in accordance with the laws in effect.
8. **National Center for Development of Drug and Food Testing**, herein referred to as **PPPOMN**, is the implementer of BPOM tasks that formulates the technical policies, carries out, monitors, evaluates, and reports the development in testing drugs and foods.
9. **Sample** is the item/object needed for the process of testing or calibration that meets certain fixed requirements and conditions.
10. **Analysis of Reference Material Certificate** is a report on the result of testing the quality of the reference material.
11. **Analysis of Reference Material Report** is a summarized report on the reference material that includes the parameters of testing and the working procedure.
12. **Microbial Certificate** is a document containing information on the identity of the microbes.
13. **Calibration Certificate** is a document containing information on the identity of the equipment that was calibrated, identity of the owner of the equipment, reference standards and conclusion of the calibration results that includes the degree of deviation, uncertainty in measurement, traceability and method of reference used.
14. **Test Certificate** is a collection of information that gives confirmation on one or more measuring scores, or information about the material that was tested in all parameters in accordance with the monography or standard requirements, using equipment as well as not using equipment.
15. **Batch/Lot Release Certificate** is an official document that allows the manufacturer to release a certain batch/lot as confirmation that the said batch/lot meets the required specifications and conditions. This certificate is issued for local vaccines and imported vaccines.
16. **Supplement Certificate/Test Report** will be issued if there are some test parameters not yet reported that do not affect or change

the conclusion of the test.

17. **Testing** is a technical activity consisting of a decision, determining one or more characteristics of a product, material, equipment, organism, phenomenon, physical condition, process or service according to the set procedures.
18. **Simple Testing** is testing conducted without or with simple instruments that give direct results of the measuring without any double interpretation.
19. **Testing with Treatment** is testing that requires a preliminary process (for example: separation by extraction) before measurement is made.
20. **Qualitative Testing of Microbiological Contamination** is testing the contamination by microbes which will disclose the existence of microbes (negative/positive).
21. **Quantitative Testing of Microbiological Contamination** is testing the contamination by microbes which will disclose the quantity/level of microbes in volume.

**PART TWO**  
**FRAMEWORK AND STANDARD PROCEDURE**  
**OF SERVICES**

**A. Framework of Procedures**

| <b>No</b> | <b>Type of Service</b> |  | <b>Time of Completion</b> | <b>Cost/Rate</b>                           | <b>Service Product</b> |
|-----------|------------------------|--|---------------------------|--|------------------------|
| 1         | Test                   | Simple test on NAPZA (Narcotics, Psychotropic drugs, and Addictive substances) | 15 days                   | According to PPNumber32 Year 2017 On Types | Certificate / Report   |
|           |                        | Test on NAPZA with treatment   | 30 days                   | and Rate on Types of                       | Certificate/ Report    |
|           |                        | Test on health equipment*  | 30 days                   | Non-Tax State                              | Certificate / Report   |
|           |                        | Simple Test on PKRT  | 15 days                   | Revenue                                    | Certificate/ Report    |
|           |                        | Test on PKRT with treatment  | 30 days                   | (PNBP) at the BPOM                         | Certificate / Report   |
|           |                        | Test on traditional medicines  | 30 days                   |  | Certificate / Report   |
|           |                        | Simple test on health supplements  | 15 days                   |  | Certificate / Report   |
|           |                        | Test on health supplements with treatment                                      | 30 days                   |  | Certificate / Report   |
|           |                        | Simple test on cosmetics (1-3 parameters)                                      | 15 days                   |  | Certificate / Report   |
|           |                        | Simple test on cosmetics (4-6parameters)                                       | 20 days                   |  | Certificate/ Report    |

|  |  |  |         |  |                      |
|--|--|--|---------|--|----------------------|
|  |  | Test on cosmetics with treatment(1-3 parameters)   | 15 days |  | Certificate / Report |
|  |  | Test on cosmetics with treatment(4-6 parameters)   | 30 days |  | Certificate / Report |
|  |  | Test on Foods                                      | 30 days |  | Certificate / Report |
|  |  | Qualitative test on microbiological contamination  | 25 days |  | Certificate/ Report  |
|  |  | Quantitative test on microbiological contamination | 25 days |  | Certificate/ Report  |

|      |   |         |   |                         |
|------|---|---------|---|-------------------------|
| Test | Test on Sterility   | 30 days | According to<br>PPNumber3<br>2 Year 2017<br>On Types<br>and Rate on<br>Types of<br>Non-Tax<br>State<br>Revenue<br>(PNBP) at<br>the BPOM | Certificate<br>/ Report |
|      | Test on Phenol<br>Coefficient   | 19 days |   | Certificate<br>/ Report |
|      | Effectiveness of<br>Preservatives   | 48 days |   | Certificate/<br>Report  |
|      | Test of Molecular<br>Biology  | 30 days |   | Certificate<br>/ Report |
|      | Test on the vaccines:<br>DT, Td,DTP, DTP-HB,<br>DTP-HB-Hib, Rabies*                               | 77 days |   | Certificate<br>/ Report |
|      | Test on vaccines:TT<br>and Bio TT ATS*  | 54 days |   | Certificate<br>/ Report |
|      | Test on vaccine:<br>BCG*  | 84 days |   | Certificate<br>/ Report |
|      | Test on vaccine:<br>OPV* and other<br>vaccines that use the<br>CellCulture Method                 | 43 days |   | Certificate<br>/ Report |
|      | Test on Measles<br>vaccine*   | 37 days |   | Certificate<br>/ Report |
|      | Test on vaccine for<br>Hepatitis B ( <i>in vitro</i> ),<br>Influenza, and<br>vaccinePolysacharide | 28 days |   | Certificate<br>/ Report |

|  |  |  |         |  |                      |
|--|--|--|---------|--|----------------------|
|  |  | Test on Endotoxin bacteria*                        | 12 days |  | Certificate / Report |
|  |  | Test on Pyrogen*                                   | 30 days |  | Certificate / Report |
|  |  | Test on Systemic Injection*                        | 26 days |  | Certificate / Report |
|  |  | Test on Acute Toxicity*                            | 63 days |  | Certificate / Report |
|  |  | Test on Primary Skin Irritation*                   | 35 days |  | Certificate / Report |
|  |  | Test on Eye Irritation*                            | 23 days |  | Certificate / Report |
|  |  | Test on Sensitization*                             | 86 days |  | Certificate / Report |
|  |  | Read histopathological preparation NVT Bulk Polio* | 30 days |  | Certificate          |
|  |  | Release of Vaccine *                               | 10 days |  | Certificate / Report |

|   |              |  |         |  |                         |
|---|--------------|--|---------|--|-------------------------|
| 2 | Calibration* | Analytic Instruments:<br>- Spectrophotometer UV/Vis (accuracy of wave length, accuracy in photometry and linearity of photometry).<br>- <i>Dissolution Tester</i> (Accuracy of temperature and rotation rate)<br>- <i>Autoclave</i> (temperature and pressure)<br>- pH meter (mV and pH) | 15 days | According to PP Number 32 Year 2017 On Types and Rate on Types of Non-Tax State Revenue (PNBP) at the BPOM | Calibration Certificate |
|---|--------------|--|---------|--|-------------------------|

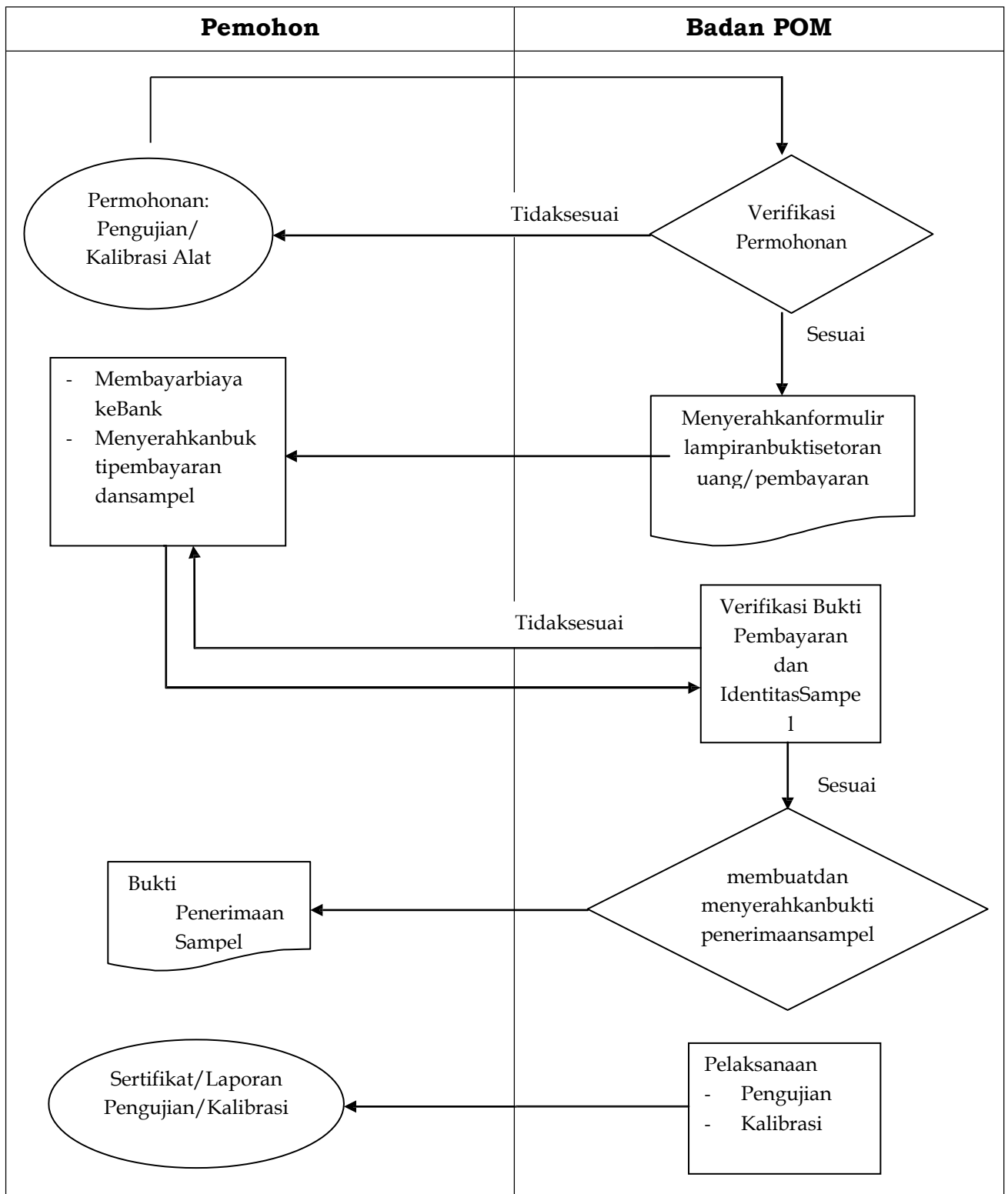
|  |  |         |  |                         |
|--|--|---------|--|-------------------------|
|  | <p>Temperature:</p> <ul style="list-style-type: none"> <li>- Enclosure (Oven, Incubator, Muffle Furnace)</li> <li>- <i>Disintegration tester,</i></li> <li>- <i>Waterbath</i></li> <li>- <i>Liquid thermometer in a glass</i></li> </ul> | 15 days |  | Calibration Certificate |
|  | <p>Mass:</p> <ul style="list-style-type: none"> <li>- Weights (max. 1000g),</li> <li>- Electronic scale (max.1000g)</li> <li>- Mechanical scale (max.1000g)</li> </ul>   | 15 days |  | Calibration Certificate |
|  | <p>Volume:</p> <ul style="list-style-type: none"> <li>- "Ex" type ( Burette, Volume pipette, Measuring pipette)</li> <li>- "IN" type (volumetric flask, measuring cup, pycnometer, Aufhauser).</li> </ul>                                | 20 days |  | Calibration Certificate |

Note :

\*) This test can only be performed at PPPOMN

## B. Procedure of Services

### Request to Conduct Tests on Drugs and Food and Calibration of Laboratory Equipment



Mechanism for the testing of drugs and food and calibration of laboratory equipment:

1. The applicant submits a request for testing/calibration by submitting/sending a letter of request for testing/calibration.
2. The officer examines the documents for completeness and compliance

with the requirements, and if all is good the process will be continued, and if not, the applicant will be asked to complete the documents.

3. The officer calculates the cost of tests/calibration according to the PNBP rate and must fill out the attached form as Proof of Payment to be delivered by the applicant to the Bank appointed as receiver and entered into the SIMPONI application (Online PNBP Information System).
4. The applicant submits Proof of Payment of the sample/object that will be tested/calibrated.
5. The officer submits Receipt of the sample for testing/calibration (Form F91009) to the applicant to be used for collecting the results of testing/calibration.
6. The officer delivers the Certificate/Report of Testing/Calibration /Release Certificate to the applicant in accordance with a pre-determined time. If the result of testing/calibration is to be collected by an assigned person, the applicant must issue a letter of authorization.

### **C. Schedule of Services**

Service Counter

Monday – Thursday : 08.00 – 16.00

Friday : 08.00–15.30

Local time

### **D. Service Facilities and Infrastructure**

1. Service Room with AC;
2. Service Desk;
3. Waiting Room;
4. Access for the Disabled;
5. Nursing Room;
6. Service Announcement;
7. Queue System (manual : *first in first out*);
8. Suggestion Box;
9. Feedback from online customers;
10. Information on electronic rate;
11. Toilet;
12. WiFi;
13. Television;

14. Mineral water;
15. Charging station;
16. Waste bin;
17. Parking lot.

## **E. Requirements**

### 1. Request for Testing Drugs and Food

Administrative Documents

Letter of Request, stating information on:

- 1) Name, address and phone number of the sample bearer
- 2) Name, address and phone number of the sample owner
- 3) Name of company, address and phone number of the company
- 4) Objective of the testing
- 5) Data and identity of the sample
  - Name of the sample
  - Type of sample
  - Batch number, and or registration number
  - Amount in terms of pieces or weight
  - Conditions of the place of storing the sample

### 2. Request for Calibration

Administrative Documents

Letter of Request, stating information on:

- 1) Name, address and phone number of the sample bearer
- 2) Name, address and phone number of the sample owner
- 3) Name of company, address and company phone number
- 4) Data and Identity of the object
  - Name of instrument
  - Brand, type/serial number
  - Originally owned by, or identity of the owner of the instrument
  - Point of measurement
  - Quantity of instruments
  - Conditions of the instrument

The applicant has the right to get information that is available regarding services in testing/calibration. Such services include :

- a. Delivering the Certificate/Report on Testing/Calibration/Release

through a courier service and showing proof of payment of the courier.

- b. Delivering the Certificate/Report on Testing/Calibration/Release through electronic means (Fax, electronic mail) will be done if the applicant has agreed that the result of testing will not be used for any purpose that is against the law, which must be declared in a written statement with sufficient revenue stamp, made by the applicant.

**F. Place of Services**

1. National Center for Development in Testing Drugs and Food of BPOM  
Jl. Percetakan Negara Number 23, Central Jakarta 10560
  
2. All Centers/Agencies for Drug and Food Control  
Specifically for the testing of drugs, NAPZA, Biopharmaceutical/Dissolution Drugs, Health Equipment, Household Health Supplies (PKRT), Traditional Medicines, Cosmetics, Health Supplements, Food and Water, Microbiological Contamination, Potential and Sterility, the services are also performed at all centers/agencies for drug and food control.

| <b>No</b> | <b>Center/ Indonesian Food and Drug Authority</b> | <b>Address</b> |
|-----------|---|----------------|
|-----------|---|----------------|

|   |   |  |
|---|---|--|
| 1 | Center for Food and Drug Authority ( <b>Balai Besar POM</b> ) in Banda Aceh | Jl. Tgk. H. Mohd. Daud Beureueh no.110<br>Banda Aceh 23126<br>Indonesia<br>Tel : 0651-23926<br>Fax : 0651-22735<br><br>email<br><a href="mailto:serliknad@yahoo.com">:serliknad@yahoo.com</a> <a href="mailto:pom_aceh@pom.go.id">pom_aceh@pom.go.id</a> |
|---|---|--|

| <b>No</b> | <b>Center/Agency for Drug and Food Control</b> | <b>Address</b>   |
|-----------|--|--|
| 2         | <i>Balai Besar POM in Medan</i>                | Jl. Willem Iskandar Psr. V Barat I No.<br>2 Medan Estate<br>Medan –North Sumatera<br>20731 Indonesia<br>Tel : 061-6628363<br>Fax : 061-6622968<br>email : <a href="mailto:bpom_medan@pom.go.id">bpom_medan@pom.go.id</a>   |
| 3         | <i>Balai Besar POM in Palembang</i>            | Jl. Pangeran Ratu Seberang<br>Ulu I South Sumatera<br>Indonesia<br>Tel : 0711-510126<br>Fax : 0711-510195<br>email<br><a href="mailto:bpomplg@yahoo.com">:bpomplg@yahoo.com</a><br><a href="mailto:bpom_palembang@pom.go.id">bpom_palembang@pom.go.id</a>        |
| 4         | <i>Balai Besar POM in Padang</i>               | Jl. Gajah Mada PO. BOX 172<br>Padang<br>West Sumatera<br>Indonesia<br>Tel : 0751-7054280<br>Fax : 0751-7055213<br>email<br><a href="mailto:bpom_padang@yahoo.com">:bpom_padang@yahoo.com</a><br><a href="mailto:bpom_padang@pom.go.id">bpom_padang@pom.go.id</a> |

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|---|--|---|
| 5 | <i>Balai Besar POM in</i><br>Pekanbaru | Jl. Diponegoro No. 10<br>Riau 28111 Indonesia<br>Tel : 0761-47879/853010<br>Fax : 0761-28755<br>Email: <a href="mailto:bpom_pekanbaru@pom.go.id">bpom_pekanbaru@pom.go.id</a> |
|---|--|---|

| <b>No</b> | <b>Center/Agency for Drug and Food Control</b> | <b>Address</b>   |
|-----------|--|--|
| 6         | <i>Balai Besar POM</i> in Bandar Lampung       | Jl. Dr. Susilo No. 105<br>Lampung 35213<br>Indonesia<br>Tel : 0721-252212<br>Fax : 0721-254888<br>email<br><a href="mailto:bpomplg@yahoo.com">:bpomplg@yahoo.com</a><br><a href="mailto:bpom_lampung@pom.go.id">bpom_lampung@pom.go.id</a>   |
| 7         | <i>Balai POM</i> in Jambi                      | Jl. RM Nur Atmadibrata No. 11<br>Jambi<br>Indonesia<br>Tel : 0741-61894<br>Fax : 0741-61894<br>email<br><a href="mailto:bpom_jambi@pom.go.id">:bpom_jambi@pom.go.id</a><br><a href="mailto:bpomjambi432835@yahoo.com">bpomjambi432835@yahoo.com</a>  |
| 8         | <i>Balai POM</i> in Bengkulu                   | Jl. Depati Payung Negara KM. 13 No. 29<br>Pekan Sabtu - Kota Bengkulu<br>Indonesia<br>Tel : 0736-53988<br>Fax: 0736-53990<br>email :<br><a href="mailto:ulpk_pombengkulu@yahoo.com">ulpk_pombengkulu@yahoo.com</a><br><a href="mailto:bpom_bgkl@yahoo.com">bpom_bgkl@yahoo.com</a><br><a href="mailto:bpom_bengkulu@pom.go.id">bpom_bengkulu@pom.go.id</a> |

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| 9 | <i>Balai POM in</i><br>Pangkalpinang | Government Office Complex<br>Bangka Belitung Islands Province,<br>Jl. Pulau Bangka, Left of the Health Affairs<br>Office, Air Itam,Pangkal Pinang<br>Bangka Belitung Indonesia<br>Tel : 0717-439278<br>Fax : -<br>email : <a href="mailto:bpom_pangkalpinang@pom.go.id">bpom_pangkalpinang@pom.go.id</a> |
|---|--------------------------------------|--|

| <b>No</b> | <b>Center/Agency for Drug and Food Control</b> | <b>Address</b>  |
|-----------|--|---|
| 10        | <i>Balai Besar POM</i> in Jakarta              | Jl. As'syafiyah no<br>133Cilangkap,East Jakarta<br>13870,<br>DKI Jakarta Indonesia<br>Tel: 021 - 3501320<br>Fax: 021 -3520219<br>email: <a href="mailto:bpom_jakarta@pom.go.id">bpom_jakarta@pom.go.id</a>  |
| 11        | <i>Balai Besar POM</i> in Bandung              | Jl. Pasteur No. 25<br>Bandung –West Java 40171<br>Indonesia<br>Tel : 022-4266620<br>Fax : 022-4213150<br>email :<br><a href="mailto:bpom_bandung@pom.go.id">bpom_bandung@pom.go.id</a>  |
| 12        | <i>Balai POM</i> in Batam                      | Complex Citramas Indah Block E28<br>Jl. HangjabatKel. Batu<br>BesarNongsaBatam<br>Indonesia<br>Tel : 0778-761543<br>Fax : -<br>email : <a href="mailto:bpom-batam@yahoo.com">bpom-</a><br><a href="mailto:bpom_batam@pom.go.id">batam@yahoo.com</a><br><a href="mailto:bpom_batam@pom.go.id">bpom_batam@pom.go.id</a> |

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| 13 | <i>Balai POM</i> in Serang | Jl. Syeh Nawawi Al-Bantani<br>Banjar Sari, Cipocok Jaya<br>Banten Indonesia<br>Tel : 0254-7168255<br>Fax : 0254-7160266<br>email : <a href="mailto:serang@pom.go.id">serang@pom.go.id</a><br><a href="mailto:bpom_serang@pom.go.id">bpom_serang@pom.go.id</a> |
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| <b>No</b> | <b>Center/Agency for Drug and Food Control</b> | <b>Address</b>   |
|-----------|--|--|
| 14        | <i>Balai Besar POM in Semarang</i>             | Jl. Madukoro Blok AA-BB No. 8<br>Semarang<br>Central Java 50144 Indonesia<br>Tel : 024-7613761<br>Fax : 024-7613633<br>email<br><a href="mailto:likpomsm@yahoo.com">:likpomsm@yahoo.com</a> <a href="mailto:bpom_semarang@pom.go.id">bpom_semarang@pom.go.id</a> |
| 15        | <i>Balai Besar POM in Yogyakarta</i>           | Jl. Tompeyan -<br>TegalorejoYogyakarta<br>Indonesia<br>Tel : 0274-552250<br>Fax : 0274-552250<br>email<br><a href="mailto:bpomjg@yahoo.co.id">:bpomjg@yahoo.co.id</a> <a href="mailto:bpom_yogyakarta@pom.go.id">bpom_yogyakarta@pom.go.id</a>                   |
| 16        | <i>Balai Besar POM in Surabaya</i>             | Jl. Karangmenjangan 20<br>Surabaya –East Java<br>Indonesia<br>Tel/Fax : 031-5020575<br>email : <a href="mailto:bpom_surabaya@pom.go.id">bpom_surabaya@pom.go.id</a>  |

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| 17 | <i>Balai Besar POM in</i><br>Denpasar | Jl. Cut Nya' Dhien No. 5<br>Renon, Bali<br>Indonesia<br>Tel/Fax : 0361-234597<br>email :<br><a href="mailto:bpom_denpasar@pom.go.id">bpom_denpasar@pom.go.id</a>  |
| 18 | <i>Balai Besar POM in</i><br>Mataram  | Jl.<br>CaturWargaMataram<br>Indonesia<br>Tel : 0370-621926<br>Fax : 0370-628033<br>email<br><a href="mailto:bpom_mtrm@yahoo.com">:bpom_mtrm@yahoo.com</a><br><a href="mailto:bpom_mataram@pom.go.id">bpom_mataram@pom.go.id</a> |

| <b>No</b> | <b>Center/Agency for Drug and Food Control</b> | <b>Address</b>   |
|-----------|--|--|
| 19        | <i>Balai POM</i> in Kupang                     | Jl. RA. Kartini -Kota Baru<br>Kel. Kelapa Lima - Kupang<br>NTT<br>Indonesia<br>Tel : 0380-8554595<br>Fax : 0380-8554595<br>email<br>: <a href="mailto:balaipom_kupang@yahoo.com">balaipom_kupang@yahoo.com</a> <a href="mailto:bpom_kupang@pom.go.id">bpom_kupang@pom.go.id</a>    |
| 20        | <i>Balai POM</i> in Palangkaraya               | Jl. CilikRiwut Km 3,5, No. 13<br>Palangkaraya–Central Kalimantan<br>Indonesia<br>Tel : 0536-3221096<br>Fax :0536-3221096<br>email<br>: <a href="mailto:bpom_palangkaraya@pom.go.id">bpom_palangkaraya@pom.go.id</a> <a href="mailto:balaipompl@yahoo.com">balaipompl@yahoo.com</a> |
| 21        | <i>Balai Besar POM</i> in Pontianak            | Jl. Dr. Soedarso PO BOX 6006<br>West Kalimantan 78124<br>Indonesia<br>Tel : 0561-572417<br>Fax :0561-737720<br>email<br>: <a href="mailto:balaipom_pontianak@yahoo.com">balaipom_pontianak@yahoo.com</a> <a href="mailto:bpom_pontianak@pom.go.id">bpom_pontianak@pom.go.id</a>    |

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| 22 | <i>Balai Besar POM</i><br>in Banjarmasin | Jl. Brigjen H. Hasan Basri No.40<br>Banjarmasin<br>South Kalimantan 70124<br>Indonesia<br>Tel : 0511-3302162<br>Fax :0511-3302162<br>email : <a href="mailto:bbpom_banjarmasin@yahoo.com">bbpom_banjarmasin@yahoo.com</a> |
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| <b>No</b> | <b>Center/Agency for Drug and Food Control</b> | <b>Address</b>  |
|-----------|--|---|
| 23        | <i>Balai Besar POM in Samarinda</i>            | Jl. Letjend. Suprpto No. 3<br>East Kalimantan<br>Indonesia<br>Tel : 0541-747743<br>Fax : 0541-741630<br>email : <a href="mailto:samarinda_ulpk@yahoo.com">samarinda_ulpk@yahoo.com</a>  |
| 24        | <i>Balai Besar POM in Makassar</i>             | Jl. BajiMinasa No. 2<br>MakasarSouth Sulawesi<br>90126 Indonesia<br>Tel : 0411-871115<br>Fax : 0411-873496<br>email<br>: <a href="mailto:ulpkmks@yahoo.com">ulpkmks@yahoo.com</a><br><a href="mailto:bpom_makassar@pom.go.id">bpom_makassar@pom.go.id</a>     |
| 25        | <i>Balai Besar POM in Manado</i>               | Jl. Raya Manado - Tomohon Km. 7<br>Pineleng–North Sulawesi<br>Indonesia<br>Tel : 0431-824327<br>Fax :0431-824210<br>email<br>: <a href="mailto:bpom_mdo@yahoo.com">bpom_mdo@yahoo.com</a><br><a href="mailto:bpom_manado@pom.go.id">bpom_manado@pom.go.id</a> |

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| 26 | <i>Balai POM</i> in Kendari | Complex BumiPrajaPemda<br>South-East Sulawesi Province<br>Andounoho - Kendari<br>South-East Sulawesi<br>Indonesia<br>Tel : 0401-3195855<br>Fax :0401-3195513<br>email<br><a href="mailto:bpom_kendari@pom.go.id">:bpom_kendari@pom.go.id</a><br><a href="mailto:ulpk_kdipom@yahoo.com">ulpk_kdipom@yahoo.com</a> |
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| <b>No</b> | <b>Center/Agency for Drug and Food Control</b> | <b>Address</b>   |
|-----------|--|--|
| 27        | <i>Balai POM</i> in Palu                       | Jl.Undata No.03<br>Palu–Central Sulawesi Indonesia<br>Tel/Fax : 0451-428738<br>email : <a href="mailto:ulpk_palu@yahoo.co.id">ulpk_palu@yahoo.co.id</a><br><a href="mailto:bpom_palu@pom.go.id">bpom_palu@pom.go.id</a>  |
| 28        | <i>Balai POM</i> in Gorontalo                  | Jl. Tengah Toto Selatan<br>Bone Bolango Gorontalo<br>Indonesia<br>Tel : 0435-8703732<br>Fax : 0435-822052<br>email<br>: <a href="mailto:ulpk_gorontalo@yahoo.co.id">ulpk_gorontalo@yahoo.co.id</a><br><a href="mailto:bpom_gorontalo@pom.go.id">bpom_gorontalo@pom.go.id</a> |
| 29        | <i>Balai POM</i> in Ambon                      | Jl. DR. Kayadoe SK.20/2 Kudamati<br>Ambon - Maluku 97116<br>Indonesia<br>Tel : 0911-342742<br>Fax : 0911-345866<br>email<br>: <a href="mailto:bpom_amq@yahoo.com">bpom_amq@yahoo.com</a><br><a href="mailto:bpom_ambon@pom.go.id">bpom_ambon@pom.go.id</a>                   |

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| 30 | <i>Balai Besar POM in</i><br>Jayapura | Jl. Diponegoro No 63<br>Jayapura 99111<br>Indonesia<br>Tel : 0967-523333<br>Fax :0967-523333<br>email<br><a href="mailto:bpomjpr04@yahoo.com">:bpomjpr04@yahoo.com</a><br><a href="mailto:bpom_jayapura@pom.go.id">bpom_jayapura@pom.go.id</a> |
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| <b>No</b> | <b>Center/Agency for Drug and Food Control</b> | <b>Address</b>   |
|-----------|--|--|
| 31        | <i>Balai POM</i> in Manokwari                  | Jl. AngkasaMulyono, Amban<br>Manokwari<br>Indonesia<br>Tel : (0986) 2217025<br>Fax : -<br>email : <a href="mailto:bpom.manokwari@yahoo.com">bpom.manokwari@yahoo.com</a> |
| 32        | <i>Balai POM</i> in Sofifi                     | Jalan Pemuda (Behind DPRD Office of<br>North Maluku )Sofifi<br>Tel :<br>Fax:<br>Email : <a href="mailto:bpom_sofifi@yahoo.com">bpom_sofifi@yahoo.com</a>                 |
| 33        | <i>Balai POM</i> in Mamuju                     | Jalan Dr. Ratulangi No. 4 Mamuju<br>West Sulawesi<br>Tel : 0822-7122-1425<br>Fax:<br>Email : <a href="mailto:bpommamuju@gmail.com">bpommamuju@gmail.com</a>              |

## **SUB-ATTACHMENT I.16**

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY  
NUMBER 27 YEAR 2018  
REGARDING  
PUBLIC SERVICE STANDARDS WITHIN THE SCOPE OF  
THE INDONESIAN FOOD AND DRUG AUTHORITY

**SERVICE STANDARDS FOR A  
REQUEST FOR REFERENCE MATERIAL AND TEST ANIMALS**

**PART ONE  
INTRODUCTION**

**A. Legal Basis**

1. Government Regulation Number 32 Year 2017 on the Types and Rate on Types of Non Tax State Revenue at the National Agency of Drug and Food Control;
2. ISO/IEC 17025:2017 on Requirements for Standard Competence of Test/Calibration Laboratories;
3. ISO 9001: 2015 on Quality Management System

**B. Purpose and Objective**

**The purpose of determining service standards** is to provide guidelines for the laboratory services within the scope of the Indonesian Food and Drug Authority and a reference for the applicants in submitting their requests for reference material, microbes, and test animals.

**The objective of service standards** is to:

- a. Provide understanding to the applicants for submitting requests for reference material, microbes, and test animals.
- b. Ensure that the request for reference material in the form of drugs, traditional medicines, health supplements, cosmetics, food, microbes and test animals by the applicant is served well in accordance with the fixed quality standards.

### C. Definition/General Meaning

1. **Reference Material** as mentioned above can be the ARS (*ASEAN Reference Substance*), BPFII (Reference Material in Pharmacopeia Indonesia) and BPL (Laboratory Reference Material)
2. **ASEAN Reference Substance** is a reference material which is tested through collaboration between the member-countries of ASEAN and its distribution in Indonesia will be arranged by PPPOMN (National Center for Development of Drug and Food Testing).
3. **Reference Material of Pharmacopeia Indonesia**, referred to as **BPFII** is a reference material that will be tested according to the monography of Pharmacopeia Indonesia, Pharmacopeia of another country or other reference, and is available at PPPOMN.
4. **Laboratory Reference Material** is material that will be tested using an official reference other than Pharmacopeia Indonesia.
5. **Test Animal Laboratory** is a laboratory that breeds and raises test animals, according to the fixed standards, to be used in laboratory testing and experiments *in vivo* for the study of vaccines, health instruments, household health supplies, cosmetics and traditional medicines.
6. **Reference Material Analysis Certificate** is a document that accompanies the reference material, which gives the results of testing according to the parameters used.

**PART TWO**  
**FRAMEWORK AND STANDARD PROCEDURE**  
**OF SERVICES**

**A. Framework of Procedures**

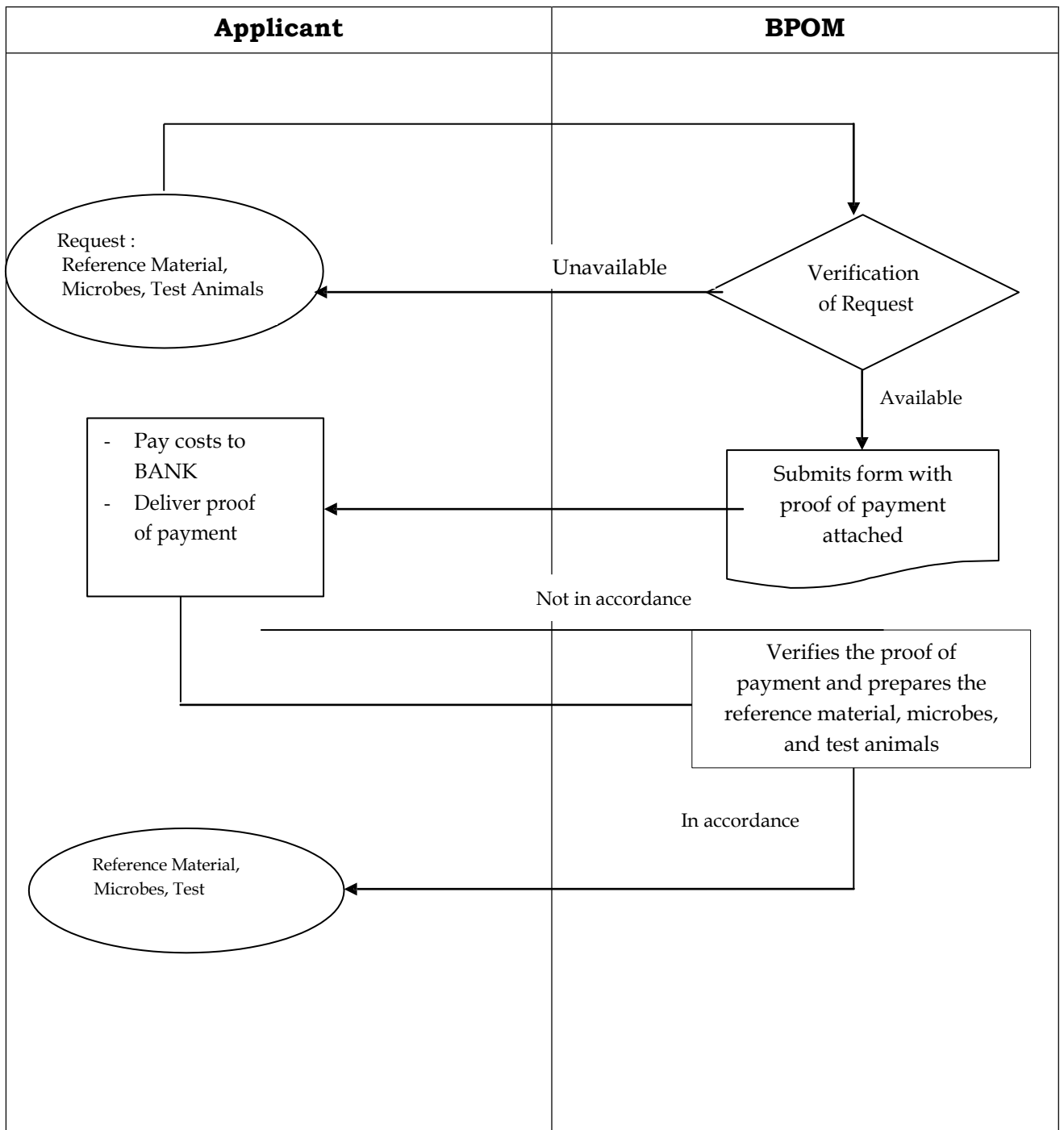
| <b>No</b> | <b>Type of Service</b>    | <b>Time of Completion</b> | <b>Cost/Rate</b>   | <b>Service Product</b>   |
|-----------|---------------------------|---------------------------|--|--|
| 1         | Reference Material        | 2 days                    | According to PPNumber32 Year 2017 on Types and Rate on Types of Non-Tax State Revenue (PNBP) at BPOM | ARS(ASEAN Reference Substance),BPFI (Reference Material of Pharmacopeia Indonesia) and BPL (Laboratory Reference Material)                                 |
| 2         | Test Animals              | 10 days                   |  | <ul style="list-style-type: none"> <li>- Rat <i>Sprague Dawley</i>,</li> <li>- Mice (white mice) ddY strain,</li> <li>- <i>Rabbit</i> JW strain</li> </ul> |
| 3         | Microbes (Micro-organism) | 7 days                    |  | <ul style="list-style-type: none"> <li>- Bacteria</li> <li>- Mold and Yeast</li> </ul>   |

Note :

The time for implementing the service is calculated as of when the form is declared complete up to the time the reference materials, microbes, test animals and analysis certificate is delivered to the applicant.

## B. Procedure of Services

### Request for Reference Material, Microbes and Test Animals



Mechanism for obtaining reference material, microbes and test animals:

The applicant must submit a letter of request and fill out a form requesting reference material, microbes, and test animals.

1. The officer examines the request file for completeness of documents and compliance to the requirements, if all is well, the process will be continued, and if not the applicant will be asked to submit the documents that are lacking.

2. The officer will calculate the cost of purchasing the reference material, microbes, and test animals according to the rates of PNBP (SIMPONI), and fill out a form to be attached as proof of payment, to be submitted by the applicant to the receiving Bank.
3. The applicant delivers the proof of payment for the reference material, microbes and test animals.
4. The officer then delivers the reference material, microbes, test animals as well as a certificate of analysis or cover letter to the applicant.

**C. Schedule of Services**

Service Counter

Monday – Thursday : 08.00 – 16.00WIB

Friday : 08.00 – 15.30WIB

**D. Service Facilities and Infrastructure**

1. Service Room with AC;
2. Service Desk;
3. Waiting Room;
4. Access for the Disabled;
5. Nursing Room;
6. Service Announcement;
7. Queue System (manual : first in first out);
8. Suggestion Box;
9. Feedback from customers online;
10. Information on rates electronically;
11. Toilet;
12. Wifi;
13. Television;
14. Mineral water;
15. Charging station;
16. Waste bin;
17. Parking Lot.

## **E. Requirements**

### 1. Request for Reference Material

Letter of request, that gives information regarding:

- a. Name, Address and Telephone Number (Individual or Company/  
Government Agency)
- b. Type of reference materials
- c. Quantity of reference materials
- d. Objective of use

### 2. Request for Microbes

Letter of request, that gives information regarding:

- a. Name, Address and Telephone Number (Individual or Company/  
Government Agency)
- b. Type of microbes (strain)
- c. Quantity of microbes
- d. Objective of use

### 3. Request for Test Animals

Letter of request, that gives information regarding:

- a. Type of test animal
- b. Male/Female
- c. Number of animals
- d. Body weight
- e. Age of the animal
- f. Planned date of pick-up
- g. Objective of using the animal
- h. Individual data or Company data

Those who have received reference material, microbes and test animals are prohibited from misusing the reference material, microbes and test animals for any purpose other than laboratory purposes or which is against the laws and regulations.

## **F. Place of Services**

Center for Development of Drug and Food Control,  
the Indonesian Food and Drug Authority

Jl. Percetakan Negara Number 23, Central Jakarta 10560

## **SUB-ATTACHMENT I.17**

REGULATION OF THE INDONESIAN FOOD AND DRUG AUTHORITY  
NUMBER 27 YEAR 2018  
REGARDING  
PUBLIC SERVICE STANDARDS WITHIN THE SCOPE OF  
THE INDONESIAN FOOD AND DRUG AUTHORITY

**SERVICE STANDARDS FOR  
REQUESTS FOR INFORMATION SERVICE AND  
THE HANDLING OF PUBLIC COMPLAINTS**

**PART ONE  
INTRODUCTION**

**A. Legal Basis**

1. Law Number 14 Year 2008 on Openness of Public Information;
2. Law Number 25 Year 2009 on Public Service;
3. Government Regulation Number 61 Year 2010 on Implementation of Law Number 14 Year 2008 on Openness of Public Information;
4. Regulation of the State Minister of Administrative and Bureaucratic Reform Number PER/05/M.PAN/4/2009 on General Guidelines For the Government Agencies to Handle Public Complaints;
5. Regulation of the Information Commission Number 1 Year 2010 on Public Information Service Standards;
6. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number HK.03.1.23.08.11.07456 Year 2011 on the Procedures of Public Information Service Within the Scope of the Indonesian Food and Drug Authority;
7. Regulation of the Chairperson of the Indonesian Food and Drug Authority Number 6 Year 2017 on List of Exempted Public Information Within the Scope of the Indonesian Food and Drug Authority;
8. Decision of the Minister of Administrative and Bureaucratic Reform Number KEP/118/M.PAN/8/2004 on General Guidelines For the Government Agencies to Handle Public Complaints;
9. Decision of the Head of BPOM Number HK.04.1.23.08.11.07457 Year 2011 on Officer for Information Management and Documentation within the scope of BPOM;
10. Decision of the Chairperson of the Indonesian Food and Drug Authority

Number HK.04.1.23.04.16.1769 Year 2016 on the Minimum Service Standards of the Public Complaints Unit within the scope of the Indonesian Food and Drug Authority.

## **B. Purpose and Objective**

**The purpose of determining service standards** is to provide guidelines for public services, namely handling public complaints and providing public information for the people, related to the control of drugs and foods.

**The objective of service standards** is to:

- a. Increase the understanding and knowledge of the people about public complaint services and information on drugs and food.
- b. Standardization of public complaint services and information includes the framework of procedures, procedures, schedule, facilities and infrastructure, requirements and public service places, in the form of settling complaints and providing information which is accurate, up-to-date, and meets the need of the customers/community with regard to drugs and food, in the context of protecting the people from drugs and food that do not fulfill the requirements of safety, efficacy/benefit, and quality.

## **C. Definition/General Meaning**

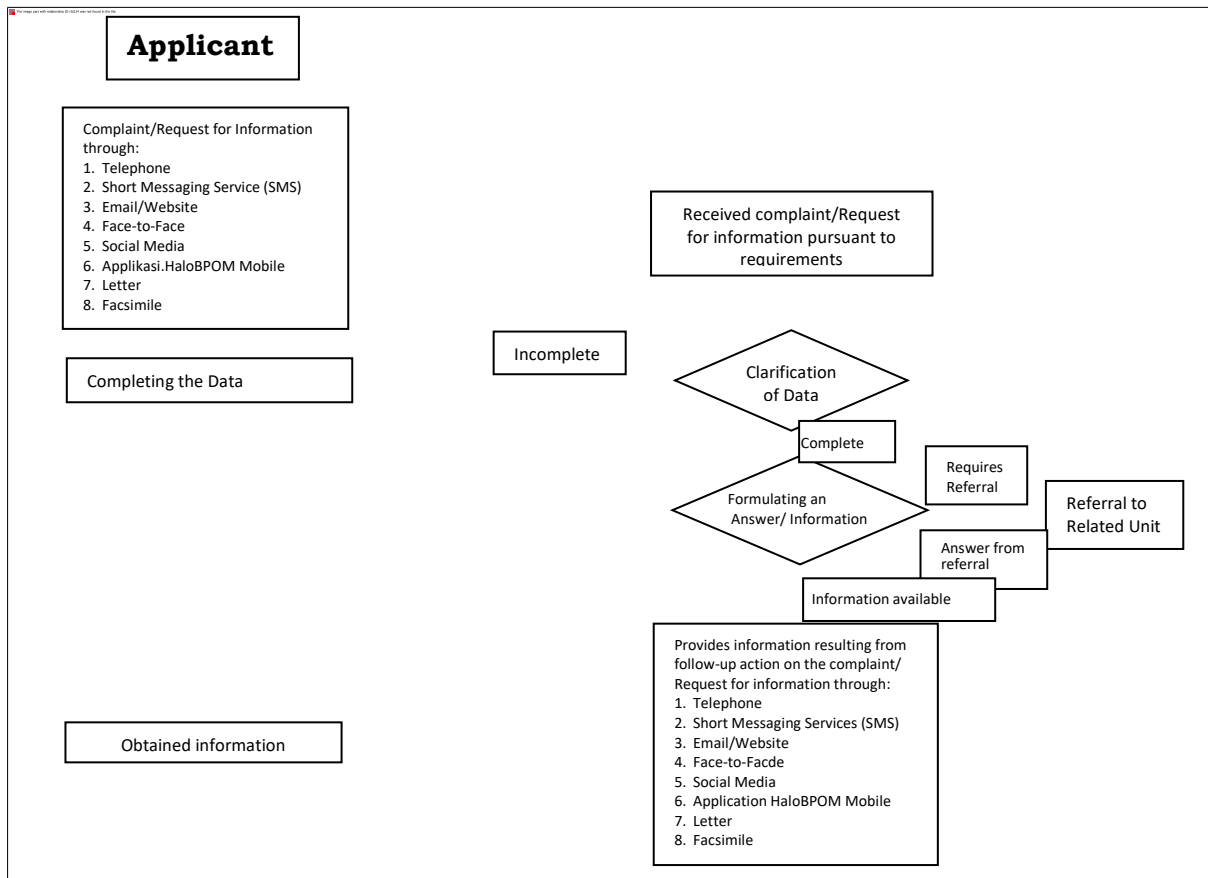
1. **Information** consists of statements, ideas, and signs that contain values, meaning and messages, in the form of data, facts and explanations that can be seen, heard, and read, presented in various wrappings and format in accordance with the developments in information technology and communication, electronically as well as non-electronically.
2. **Public Information** is information which is produced, stored, managed, sent, and/or received by a public entity which is linked to the administrators and state administration and/or the administrators and administration of another public entity in accordance with the laws and regulations in effect, and other information related to the public interests.
3. **Public Complaint** is a complaint submitted by the public to the Contact Center and/or Consumer Complaint Service Unit (ULPK) of the Center/ Agency of Drug and Food Control, in the form of a complaint related to drug and food control.

| <b>No.</b> | <b>Type of Service</b> | <b>Service Media</b>   | <b>Time of Completion</b> | <b>Cost/ Rate</b>       | <b>Service Product</b>                            |
|------------|------------------------|--|---------------------------|-------------------------|---|
| 1.         | Information available  | <ul style="list-style-type: none"> <li>- Telephone</li> <li>- Short Messaging Services (SMS)</li> <li>- Email/ Web site</li> <li>- Face-to-Face</li> <li>- Social Media</li> <li>- Application Halo BPOM Mobile</li> </ul> | 1 work day                | No cost/ free of charge | Information and follow-up action to the complaint |
|            |                        | <ul style="list-style-type: none"> <li>- Letter</li> <li>- Facsimile</li> </ul>  | 7 work days               |                         |   |

|    |                     |   |  |  |  |
|----|---------------------|---|--|--|--|
| 2. | Requires a referral | <ul style="list-style-type: none"> <li>- Telephone</li> <li>- Short Messaging Services (SMS)</li> <li>- Email/</li> <li>- Website</li> <li>- Face-to-Face</li> <li>- Social Media</li> <li>- Application Halo BPOM Mobile</li> <li>- Letter</li> <li>- Facsimile</li> </ul> | 10 work days and can be extended up to 7 work days with prior notice |  |  |
|----|---------------------|---|--|--|--|

**PART TWO**  
**FRAMEWORK AND STANDARD PROCEDURE**  
**OF SERVICES**

**A. Procedure of Services**



**B. Schedule of Services\***

1. Telephone/Face-to-Face

- Monday-Thursday:  
 Service hours : 08.30-16.00  
 Break : 12.00 -13.00
- Friday:  
 Service hours : 08.30-15.30  
 Break : 11.30 -13.30

2. *Short Messaging Services (SMS)/ Social Media*  
*/ApplicationHaloBPOM Mobile/Letter /Facsimile*

- Monday-Thursday:  
 Service hours : 08.30 -16.00
- Friday :  
 Service hours : 08.30 -15.30

- Complaints/requests for information that are submitted outside of office hours will be given a response during working hours of the next day.
3. Email/Website: 24 Jam (*autoreplay*)

\* local time

### **C. Service Facilities and Infrastructure**

1. Service Room;
2. Service Chair;
3. Service Desk;
4. Suggestion Box;
5. Computer;
6. Waiting Room;
7. Toilet;
8. Parking Lot; and
9. Reference.

### **D. Requirements**

1. Identity of the Applicant (name, telephone number/email/address/social media account, occupation/profession, ID Card/Identification sign for face-to-face services);
2. Identity of the product being compared;
3. Type of information needed; and
4. Purpose of requesting information

### **E. Place of Services**

Indonesian Food and Drug Authority

Jl. Percetakan Negara No.23, Central Jakarta

10560 Telephone : 021-4263333/021-

42889117/021-4240231

Facsimile: 021-4263333

Email: [ulpk@pom.go.id](mailto:ulpk@pom.go.id);and

[ulpk\\_badanpom@yahoo.co.id](mailto:ulpk_badanpom@yahoo.co.id)SMS :

081219999533

Twitter : @halobpom1500533

Instagram :  
@halobpom1500533\_

1. All centers/agencies for drug and food control :

| <b>No</b> | <b>Center/Agency of Drug and Food Control</b>                                   | <b>Address</b>   |
|-----------|---|--|
| 1         | <b>Balai Besar POM</b><br>(Center/Agency of Drug and Food Control)in Banda Aceh | Jl. Tgk. H. Mohd. Daud Beureueh<br>No.110 Banda Aceh 23126<br>Indonesia<br>Tel : 0651-23926<br>Fax : 0651-22735<br>Email: <a href="mailto:bpom_aceh@pom.go.id">bpom_aceh@pom.go.id</a><br>Twitter : @BPOMAceh<br>Facebook : BPOM Aceh<br>Instagram : @bpomaceh   |
| 2         | <i>Balai Besar POM in Medan</i>   | Jl. Willem Iskandar Psr. V Barat I<br>No. 2 Medan Estate-Medan,<br>North Sumatera 20731<br>Indonesia<br>Tel : 061-6622968<br>Fax : 061-6622968<br>Email: <a href="mailto:bpom_medan@pom.go.id">bpom_medan@pom.go.id</a><br>Twitter : @BPOMMedan<br>Facebook : Bbpom di Medan<br>Instagram : @bpommedan |
| 3         | <i>Balai Besar POM in Palembang</i>   | Jl. Pangeran Ratu SU I Jakabaring-<br>Palembang, South Sumatera  |

Indonesia

Tel : 0711-510126

Fax : 0711-510195

Email :

[bpom\\_palembang@pom.go.id](mailto:bpom_palembang@pom.go.id).

Twitter : [@BPOM\\_Palembang](https://twitter.com/BPOM_Palembang)

Facebook :Balai Besar POM in  
Palembang

Instagram : [@bbpom.palembang](https://www.instagram.com/bbpom.palembang)



| <b>No</b> | <b>Center/Agency of Drug and Food Control</b> | <b>Address</b>  |
|-----------|---|---|
| 7         | <i>Balai POM</i> in Jambi                     | Jl. R.M Nuratmadibrata No. 11,<br>Telanai Pura, Jambi, 36123<br>Indonesia<br>Tel. :0741-64077<br>Fax. :0741-61031<br>Email<br>: <a href="mailto:bpomjambi432835@yahoo.com">bpomjambi432835@yahoo.com</a><br><a href="mailto:bpom_jambi@pom.go.id">bpom_jambi@pom.go.id</a><br>Twitter : @bpom_jambi<br>Facebook :Bpom Jambi<br>Instagram : @bpomjambi         |
| 8         | <i>Balai POM</i> in Bengkulu                  | Jln. DepatiPayung Negara KM.13 No.29<br>Pekan SabtuTromol Pos 2, Bengkulu<br>38213<br>Indonesia<br>Tel : 0736-53990/53993/53989<br>Fax: 0736-<br>53988/53993/53989<br>Email :bpom_bengkulu@pom.go.id,<br><a href="mailto:bpom_bgkl@yahoo.com">bpom_bgkl@yahoo.com</a><br>Twitter : @BPOMBengkulu<br>Facebook : BPOM di Bengkulu<br>Instagram : @bpom_bengkulu |

|   |                                   |   |
|---|-----------------------------------|---|
| 9 | <i>Balai POM</i> inPangkal Pinang | Government Office Complex,<br>Bangka Belitung Islands, Jl. Pulau<br>Bangka, Air Itam, Pangkal Pinang -<br>Bangka Belitung<br>Tel : 0717-439278<br>Email :bpomplg@gmail.com<br><a href="mailto:bpom_pangkalpinang@pom.go.id">bpom_pangkalpinang@pom.go.id</a><br>bpomplg@yahoo.com<br>Twitter : @BPOMPklPinang<br>Facebook :Balai POM inPangkalpinang<br>Instagram : @bpom.pangkalpinang |
|---|-----------------------------------|---|

| <b>No</b> | <b>Center/Agency of Drug and Food Control</b> | <b>Address</b>  |
|-----------|---|---|
| 10        | <i>Balai Besar POM</i> in Jakarta             | Jl. As'syafiyah No. 133,<br>Cilangkap, East Jakarta<br>Tel. :021-84304047/84304049<br>Fax. :021-84304046/84304048<br>Email :bbpomjkt@gmail.com<br><a href="mailto:bpom_jakarta@pom.go.id">bpom_jakarta@pom.go.id</a><br>Twitter : @BPOMJakarta<br>Facebook :Bpom Jakarta<br>Instagram :@bbpom_jakarta |
| 11        | <i>Balai Besar POM</i> in Bandung             | Jl. Pasteur No. 25<br>Bandung –West Java 40171<br>Indonesia<br>Tel : 022-4230546<br>Fax : 022-4200382<br>Email : <a href="mailto:bpom_bandung@pom.go.id">bpom_bandung@pom.go.id</a><br>Twitter : @BPOMBandung<br>Facebook : BBPOM in Bandung<br>Instagram : @bpombandung                              |

|    |                           |   |
|----|---------------------------|---|
| 12 | <i>Balai POM</i> in Batam | Complex Citramas Indah Blok E28<br>Jl. Hang Jebat Kelurahan Batu<br>BesarNongsa,Batam<br>Indonesia<br>Tel : 0778-761025<br>Email <a href="mailto:1:bpom_batam@pom.go.id">1:bpom_batam@pom.go.id</a><br><br>Twitter : @BPOMBatam<br><br>[Facebook :Balai Pom in Batam<br>Instagram : @bpom.batam |
|----|---------------------------|---|

| No | Center/Agency of Drug and Food Control | Address   |
|----|--|---|
| 13 | <i>Balai POM</i> in Serang             | Jl. Syeh Nawawi Al-Bantani<br>Banjarsari Cipocok Jaya<br>Banten<br>Indonesia<br>Tel : 0254-8490943/8491152<br>Fax : 0254-8491153<br>Email : <a href="mailto:balaipomserang@yahoo.com">balaipomserang@yahoo.com</a><br>bpom_serang@pom.go.id<br>Twitter : @BPOM_Serang<br>Facebook :Balai POM Serang<br>Instagram : @bpom_serang |
| 14 | <i>Balai Besar POM</i> in Semarang     | Jln. Sukun Raya Number 41 A,<br>Banyumanik, Semarang<br>Central Java 50264<br>Indonesia<br>Tel : 024-7613761<br>Fax : 024-7613633<br>Email :bpom_semarang@pom.go.id<br><br>Twitter : @bpomsemarang<br>Facebook :Balai Besar POM in Semarang<br>Instagram : @bpomsemarang  |
| 15 | <i>Balai Besar POM</i> in Yogyakarta   | Jl. Tompeyan – Tegalrejo<br>Yogyakarta 55244<br>Indonesia<br>Tel : 0274-552250/561038<br>Fax : 0274-552250/519052<br>Email :bpom_yogyakarta@pom.go.id<br>bbpomjg@yahoo.co.id<br><br>Twitter : @BPOM_Yogya   |

|  |  |  |
|--|--|--|
|  |  | Facebook :BalaiBesar POM Yogyakarta<br>Instagram : @bbpom_yogyakarta |
|--|--|--|

| <b>No</b> | <b>Center/Agency of Drug and Food Control</b> | <b>Address</b>  |
|-----------|---|---|
| 16        | <i>Balai Besar POM</i> in Surabaya            | Jl. Karangmenjangan 20<br>Surabaya –East Java<br>Indonesia<br>Tel/Fax : 031-5020575<br>Email : <a href="mailto:bpom_surabaya@pom.go.id">bpom_surabaya@pom.go.id</a><br><a href="mailto:bbpom_surabaya@yahoo.co.id">bbpom_surabaya@yahoo.co.id</a><br>Twitter : @Bpom_Surabaya<br>Facebook : BBPOM Surabaya<br>Instagram : @bbpom_surabaya |
| 17        | <i>Balai Besar POM</i> in Denpasar            | Jl. Cut NyakDien No. 5 Renon<br>Bali Indonesia<br>Tel. :0361-225395<br>Fax. :0361-225395<br>Email : <a href="mailto:pomdenpasar@yahoo.co.id">pomdenpasar@yahoo.co.id</a><br><a href="mailto:bpom_denpasar@pom.go.id">bpom_denpasar@pom.go.id</a><br>Twitter : @BPOMDenpasar<br>Facebook : BBPOM Denpasar<br>Instagram : @bpomdenpasar     |

|    |                                   |   |
|----|-----------------------------------|---|
| 18 | <i>Balai Besar POM</i> in Mataram | Jl. Catur Warga Mataram,<br>Nusa Tenggara Barat 83121<br>Indonesia<br>Tel : 0370-621926<br>Fax : 0370-628033<br>Email : <a href="mailto:bpom_mtrm@yahoo.com">bpom_mtrm@yahoo.com</a><br><a href="mailto:bpom_mataram@pom.go.id">bpom_mataram@pom.go.id</a><br>Twitter : @BBPOMMataram<br>Facebook : BbpomNtb<br>Instagram : @bbpommataram |
|----|-----------------------------------|---|

| No | Center/Agency of Drug and Food Control | Address   |
|----|--|---|
| 19 | <i>Balai POM</i> in Kupang             | Jl. RA. Kartini, Kelapa Lima, Kupang-NTT Indonesia<br>Tel : 0380-8554595<br>Fax : 0380-8554595<br>Email : <a href="mailto:balaipom_kupang@yahoo.com">balaipom_kupang@yahoo.com</a><br>bpom_kupang@pom.go.id<br>Twitter : @BPOMKupang<br>Facebook :Balai POM inKupang<br>Instagram : @bpomkupang |
| 20 | <i>Balai POM</i> in Palangkaraya       | Jl. Cilik Riwut Km 3.5 No. 13<br>Palangkaraya–Central Kalimantan Indonesia<br>Tel : 0536-3221096<br>Fax :0536-3221096<br>Email :balaipomplk@yahoo.com<br>Twitter : @BPOMPalangka<br>Facebook :Balai Pom inPalangkaraya<br>Instagram : @bpom_palangkaraya  |

|    |                                     |  |
|----|-------------------------------------|--|
| 21 | <i>Balai Besar POM in Pontianak</i> | Jl. Dr. Soedarso PO BOX 6006 West Kalimantan 78124<br>Indonesia<br>Tel : 0561-572417<br>Fax :0561-737720<br>Email : <a href="mailto:balaipom_pontianak@yahoo.com">balaipom_pontianak@yahoo.com</a><br><br><a href="mailto:bpom_pontianak@pom.go.id">bpom_pontianak@pom.go.id</a><br>Twitter : @BPOMPontianak<br>Facebook : BBPOM Pontianak<br>Instagram : @bbpom_pontianak |
|----|-------------------------------------|--|

| <b>No</b> | <b>Center/Agency of Drug and Food Control</b> | <b>Address</b>  |
|-----------|---|---|
| 22        | <i>Balai Besar POM</i> in Banjarmasin         | Jl. Brigjen H. Hasan Basri No.40<br>Banjarmasin South Kalimantan<br>70124<br>Indonesia<br>Tel : 0511-3302162/3305115/3304286<br>Fax : 0511-3302162<br>Email :bbpom_banjarmasin@yahoo.com<br><br>bpom_banjarmasin@pom.go.id<br>Twitter : @BPOMBanjarmasin<br>Facebook :Bbpom Banjarmasin<br>Instagram : @BBPOM_Banjarmasin |
| 23        | <i>Balai Besar POM</i> in Samarinda           | Jl. Letjend. Suprpto No. 3<br>East Kalimantan<br>Indonesia<br>Tel. :0541-741630<br>Fax.:0541-747743<br>Email :bpom_samarinda@pom.go.id<br>bbpom_smd@yahoo.com<br>Twitter : @BPOM_Samarinda<br>Facebook :Bbpom di Samarinda<br>Instagram : @Bbpom_samarinda_   |
| 24        | <i>Balai Besar POM</i> in Makassar            | Jl. BajiMinasa No. 2 Makasar<br>South Sulawesi 90126<br>Indonesia<br>Tel : 0411-871115<br>Fax : 0411-873496<br>Email :ulpkmks@yahoo.com<br><br>bpom_makassar@pom.go.id<br><br>Twitter : @BPOMMakassar   |

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|--|--|---|
|  |  | Facebook :Balai Besar POM in Makassar<br>Instagram : @bbpommakassar |
|--|--|---|

| No | Center/Agency of Drug and Food Control | Address   |
|----|--|---|
| 25 | <i>Balai Besar POM</i> in Manado       | <p>Jl. Raya Manado - Tomohon Km. 7<br/> Pineleng–North Sulawesi Indonesia<br/> Tel: 0431-824686<br/> Fax. : 0431-824210<br/> Email<br/> :<a href="mailto:pommanado@yahoo.co.id">pommanado@yahoo.co.id</a><br/> <a href="mailto:manado@pom.go.id">manado@pom.go.id</a></p> <p>Twitter : @BPOMManado<br/> Facebook : BBPOM in Manado<br/> Instagram :@bbpom_manado</p>                                  |
| 26 | <i>Balai POM</i> in Kendari            | <p>Complex Bumi Praja Pemda<br/> Andounoho Kendari -<br/> Southeast Sulawesi<br/> Indonesia<br/> Tel : 0401-3195855<br/> Fax :0401-3195513<br/> Email :<a href="mailto:bpom_kendari@pom.go.id">bpom_kendari@pom.go.id</a><br/> <a href="mailto:ulpk_kdipom@yahoo.com">ulpk_kdipom@yahoo.com</a><br/> Twitter : @bpomkendari<br/> Facebook :Balai POM in Kendari<br/> Instagram : @bpom_di_kendari</p> |

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|----|--------------------------|---|
| 27 | <i>Balai POM</i> in Palu | Jl.Undata No.03 Palu–<br>Central Sulawesi, Indonesia<br>Tel/Fax : 0451-428738<br>Email : <a href="mailto:ulpk_palu@yahoo.co.id">ulpk_palu@yahoo.co.id</a><br><a href="mailto:bpom_palu@pom.go.id">bpom_palu@pom.go.id</a><br>Twitter : @bpompalu<br>Facebook : Balai Pom Palu<br>Instagram : balai_pom_palu |
|----|--------------------------|---|

| <b>No</b> | <b>Center/Agency of Drug and Food Control</b> | <b>Address</b>  |
|-----------|---|---|
| 28        | <i>Balai POM</i> in Gorontalo                 | Jl. Tengah Toto Selatan Bone<br>Bolango, Gorontalo<br>Indonesia<br>Tel : 0435-822052<br>Fax : 0435-822052<br>Email : <a href="mailto:ulpk_gorontalo@yahoo.co.id">ulpk_gorontalo@yahoo.co.id</a><br><br>bpom_gorontalo@pom.go.id<br>Twitter : @Gorontalo_BPOM<br>Facebook : Balai Pom in Gorontalo<br>Instagram : @bpomgorontalo |
| 29        | <i>Balai POM</i> in Ambon                     | Jl. DR. Kayadoe SK.20/2<br>Kudamati Ambon<br>Maluku 97116<br>Indonesia<br>Tel : 0911-342742<br>Fax : 0911-345866<br>Email : <a href="mailto:bpom_ambon@pom.go.id">bpom_ambon@pom.go.id</a><br><br>bpom_ambon@yahoo.com<br>Twitter : @BPOMAmbon<br>Facebook : Balai POM in Ambon<br>Instagram : @balaipomambon                   |
| 30        | <i>Balai Besar POM</i> in Jakarta             | Jl. Gurabesi No. 63<br>Kotak POS 1415<br>Jayapura<br>Indonesia<br>Tel : 0967-523333<br>Fax : 0967-523333  |

Email :bpom\_j

[ayapura@pom.go.id,](mailto:ayapura@pom.go.id)

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