

**HEAD OF NATIONAL AGENCY OF DRUG AND FOOD CONTROL
OF THE REPUBLIC OF INDONESIA
REGULATION
NO: HK.03.1.23.12.11.1.10690 YEAR 2011
ON
IMPLEMENTATION OF PHARMACOVIGILANCE
FOR PHARMACEUTICAL INDUSTRY**

Considering : that in order to implement Article 9 paragraph (3) of Minister of Health Regulation No. 1799/Menkes/Per/XII/2010 on Pharmaceutical Industry, it is deemed necessary to stipulate the the Head of the National Agency of Drug and Food Control Regulation on Implementation of Pharmacovigilance for Pharmaceutical Industry.

In view of :

1. Act No. 5 of 1997 on Psychotropic (State Gazette of 1997 Number 10, Supplement to State Gazette Number 3671);
2. Act No. 8 of 1999 on Consumer Protection (State Gazette of 1999 Number 42, Supplement of State Gazette Number 3821);
3. Act No. 35 of 2009 on Narcotics (State Gazette of 2009 Number 143, Supplement of State Gazette Number 5062);
4. Act No. 36 of 2009 on Health (State Gazette of 2009 Number 144, Supplement of State Gazette Number 5063);
5. Presidential Decree No. 103 of 2001 on Status, Task, Function, Authority, Organizational Structure and Working Procedure of Non-Departmental Government Institution, as amended by Presidential Decree No. 64/ 2005;
6. Presidential Decree No. 110 of 2001 on Organizational Unit and Duties of Echelon I within Non-Departmental Government Institutions, as amended by the Presidential Decree No. 52/2005;

7. Minister of Health Regulation No. 1010/Menkes/Per/XI/2008 on Drug Registration, as amended by Minister of Health Regulation No. 1120/Menkes/Per/XII/2008;
8. Minister of Health Regulation No. 1799/Menkes/Per/XII/2010 on Pharmaceutical Industry;
9. Head of the National Agency of Drug and Food Control Decree No. 02001/SK/KBPOM of 2001 on Organization and Work Procedures of the National Agency of Drug and Food Control, as amended by the Head of the National Agency of Drug and Food Control Decree No. HK.00.05.21.4231 of 2004;
10. Head of the National Agency of Drug and Food Control Regulation No. HK.03.1.23.10.11.08481 of 2011 on Criteria and Procedure of Drug Registration;

DECIDES

To stipulate : HEAD OF NATIONAL AGENCY OF DRUG AND FOOD CONTROL OF THE REPUBLIC OF INDONESIA REGULATION ON IMPLEMENTATION OF PHARMACOVIGILANCE FOR PHARMACEUTICAL INDUSTRY.

CHAPTER I

GENERAL PROVISION

Article 1

Refer to this Regulation, the definitions of:

1. **Drug** is a substance or combination of substances, including biological products, being used in human to modify or examine the physiological system or the pathological

condition for the purposes of diagnosis, prevention, cure, recovery, health improvement and contraception.

2. **Biological products** are vaccine, immunosera, antigen, hormone, enzyme, blood product and other fermentation products (including monoclonal antibody and products derived from recombinant DNA technology) being used to modify or examine physiological system or pathological condition for the purposes of prevention, cure, recovery and health improvement.
3. **Pharmaceutical Industry** is a company holding a permit from the Ministry of Health to manufacture finished drugs or substances.
4. **Pharmacovigilance** is the science and activity relating to the detection, assessment, understanding and prevention of adverse effects or any other possible drug-related problems.
5. **The Head of Agency** is the head of the National Agency of Drug and Food Control of the Republic of Indonesia.

CHAPTER II

PHARMACOVIGILANCE

Article 2

- (1) Pharmaceutical Industry has an obligation to conduct Pharmacovigilance.
- (2) Pharmacovigilance as referred to in paragraph (1) is carried out by undertaking surveillance and reporting on:
 - a. safety issues of drugs for the purposes of detection, assessment, understanding and prevention of adverse effects or any other drug-related problems;
 - b. changes in the benefit-risk profiles of drugs; and/or
 - c. quality issues that may have impact on the safety of drugs.

CHAPTER III
REPORTING AND DOCUMENTATION

Article 3

- (1) In the case where Pharmaceutical Industry, while conducting Pharmacovigilance activities as referred to in Article 2, finds its manufactured drugs and/or substances do not meet the standards and/or requirements for safety, efficacy/benefit and quality, the Pharmaceutical Industry must report the findings to the Head of Agency.
- (2) Reporting as referred to in paragraph (1) consists of:
 - a. spontaneous reporting;
 - b. periodic safety update reporting;
 - c. post-marketing safety surveillance reporting;
 - d. published case/scientific literature reporting;
 - e. reporting of actions taken by Regulatory Authorities of other countries;
 - f. reporting of actions taken by marketing authorization holders in other countries;
and/or
 - g. reporting of risks management planning.
- (3) Spontaneous reporting as referred to in paragraph (2) may include serious adverse events and non-serious adverse events associated with the use drugs, including vaccines.
- (4) Criteria for serious adverse events as referred to in paragraph (3) include all medical occurrences that:
 - a. results in death;
 - b. is life threatening;
 - c. requires hospitalization;
 - d. prolongs hospitalization;
 - e. causes permanent disability;

- f. results in congenital anomalies; and/or
 - g. other significant medical occurrences.
- (5) Terms of the types of reports and period covered in Pharmacovigilance as referred to in paragraph (1) are laid out in the attached Guideline.

Article 4

- (1) The Pharmacovigilance reports as referred to in Article 3 are subject to evaluation by the Head of Agency.
- (2) Evaluation as referred to in paragraph (1) can be carried out together with a Team of Experts assigned by the Head of Agency.
- (3) Results of the evaluation as referred to in paragraph (1) and paragraph (2) will be given to the Pharmaceutical Industry for follow-up.

Article 5

- (1) Pharmaceutical Industry has an obligation to keep good record of all Pharmacovigilance data and reports.
- (2) Pharmacovigilance data and reports as referred to in paragraph (1) should be shown to the authorized inspectors.

CHAPTER IV

TECHNICAL GUIDELINE

Article 6

The conduct of Pharmacovigilance as referred to in Article 2, Article 3 and Article 5 must be kept in line with the Technical Guideline set out in the Annex incorporated into this Regulation.

CHAPTER V

ADMINISTRATIVE SANCTIONS

Article 7

Pharmaceutical Industry that fails to fulfill the Pharmacovigilance provisions set out in this Regulation shall be subject to administrative sanctions in the form of:

- a. written warning;
- b. temporary suspension of distribution and/or order for withdrawal from distribution the finished drug or substance that does not meet the standards and requirements for safety, efficacy/benefit, or quality;
- c. order for destruction of finished drug or substance, if proven failed to meet the safety, efficacy/benefit and quality requirements; and/or
- d. temporary suspension of manufacture activities.

CHAPTER VI

TRANSITIONAL PROVISION

Article 8

Pharmaceutical Industry shall make necessary adjustment to comply with provisions of this Regulation not later than 24 (twenty four) months after the Regulation is enacted.

CHAPTER VII

CONCLUSION

Article 9

This Regulation shall become effective since the date of its enactment.

In order for the Regulation to be made publicly, therefore it is ordered the publication of this Regulation in the Republic of Indonesia State Gazette.

Stipulated in Jakarta

On 30 December 2011

Head of the National Agency of Drug and Food Control

Republic of Indonesia,

KUSTANTINAH

Enacted in Jakarta

On 5 January 2012

Ministry of Law and Human Right

Republic of Indonesia,

AMIR SYAMSUDIN

State Gazette Republic of Indonesia Year 2012 Number 29

ANNEX

HEAD OF NATIONAL AGENCY OF DRUG AND FOOD CONTROL REGULATION

NO. HK.03.1.23.12.11.10690 YEAR 2011

ON IMPLEMENTATION OF PHARMACOVIGILANCE FOR PHARMACEUTICAL INDUSTRY

TECHNICAL GUIDELINE FOR IMPLEMENTATION OF PHARMACOVIGILANCE FOR PHARMACEUTICAL INDUSTRY

1. BACKGROUND

The National Agency of Drug and Food Control (BPOM) has mandate to enforcing drugs and food control in order to protect the public from sub-standard drugs and food. With respect to drugs control, BPOM undertakes the safeguarding and monitoring of the safety, efficacy, and quality aspects of drugs starting from pre-marketing phase to post-marketing surveillance.

In the scope of post-marketing surveillance, the monitoring of drugs safety aspects is a strategic measure for ensuring drug safety. This activity, in turn, will have impact on ensuring patients safety as end-users of drugs.

The post-marketing drugs safety surveillance is meant to determine the effectiveness and safety of drugs in real-life setting or actual clinical practice. Many evidences have suggested that adverse drug reactions can actually be avoided as deeper knowledge being accumulated through, among other things, post-marketing drug safety surveillance. In this light, such undertaking becomes one of the important components within the overall system of drug regulation, clinical practice and public health.

Apart from the supervision undertaken by BPOM, the Pharmaceutical Industry has role and responsibility to guarantee the safety of their marketed products. These obligations are laid down in Article 9 of Minister of Health Decree No. 1799/Menkes/Per/XII/2010 dated 16 December 2010, which states that the Pharmaceutical Industry must conduct Pharmacovigilance. In the case where Pharmaceutical Industry, while conducting Pharmacovigilance activities, finds its manufactured drugs and/or substances do not meet the standards and/or requirements for safety, efficacy/benefit and quality, the Pharmaceutical Industry must report the findings to the Head of Agency. Particularly with respect to the Pharmaceutical Industry's role and responsibility in ensuring the safety of their marketed products, the Pharmaceutical Industry has an obligation undertake the post-marketing monitoring and reporting on drugs safety issues. In order to fulfill such obligation, a Technical Guideline for Pharmacovigilance is necessary to provide guidance for the Pharmaceutical Industry.

II. PURPOSE AND SCOPE

This Technical Guideline is principally meant to provide guidance for Pharmaceutical Industry for conducting Pharmacovigilance. It prescribes the minimum requirements the Pharmaceutical Industry must meet in order to fulfill their responsibility in ensuring the safety of their marketed products. The scope of the Guideline consists of: organization, spontaneous reporting, Periodic Safety Update Report (PSUR), post-marketing safety surveillance reporting, published case reporting, reporting of actions taken by Regulatory Authorities in other countries, reporting of actions taken by marketing authorization holders in other countries, and reporting of risks management planning.

III. ROLE AND RESPONSIBILITY OF PHARMACEUTICAL INDUSTRY

Pharmaceutical Industry's role and responsibility with regard to Pharmacovigilance are set forth in Article 9 of the Minister of Health Decree No. 1799/Menkes/Per/XII/2010 dated

16 December 2010 on Pharmaceutical Industry, which stipulates that the Pharmaceutical Industry has an obligation to conduct Pharmacovigilance.

In this regard, Pharmaceutical Industry is required to have an adequate Pharmacovigilance system in place to support their undertaking of the post-marketing safety surveillance of their marketed products. The Pharmacovigilance system must be designed in a manner that reflects the Pharmaceutical Industry's responsibility and capacity to take necessary actions in guaranteeing the safety of their marketed products. The Pharmacovigilance system built by the Pharmaceutical Industry must have written procedures describing activities including the processes of collecting and receiving data, evaluating and reporting of drug safety issues, as well as undertaking necessary follow-up measures.

IV. ROLE OF DRUG AND FOOD CONTROL AGENCY

In accordance with its assigned tasks and functions, BPOM undertakes pre- and post-marketing surveillance of drugs in distribution. The post-marketing surveillance is carried out through, among other things, the conduct of Pharmacovigilance System that aims to monitor, collect and evaluate all information on safety issues so it could pass judgment on the benefits and risks of drugs approved for distribution in Indonesia. BPOM continues to monitor the safety aspects of drugs in distribution and takes necessary follow-up regulatory actions in that regard.

The regulatory actions taken by BPOM may take the form of changing of product information (including, but not limited to, changing of indications, posology and dose limitation), limitation of usage, suspension of distribution license, cancelation of distribution license, and withdrawal of products from distribution.

V. PHARMACOVIGILANCE SYSTEM

V. 1. Organization

Pharmaceutical Industry is required to have a Pharmacovigilance system that is implemented as a form of their responsibility over their marketed drugs. The system should ensure the Pharmaceutical Industry is able to take appropriate actions as necessary. The Pharmaceutical Industry must make sure that all latest safety-related information such as updated risk-benefit balance of their marketed drugs be reported immediately to BPOM.

Pharmaceutical Industry must have a unit within its organization dedicated to undertake Pharmacovigilance activities. The unit could be a newly set up or an existing unit with newly-assigned additional functions for Pharmacovigilance management.

The abovementioned unit should be reflected in the existing organization structure, along with description of its tasks and functions, including its working relation with other units within the organization with regard to the Pharmacovigilance implementation.

In implementing Pharmacovigilance, the Pharmaceutical Industry must assign a qualified person responsible for Pharmacovigilance activities. The person responsible for Pharmacovigilance should at least possess relevant education background and/or has undertaken training in Pharmacovigilance.

Duties of the person responsible for Pharmacovigilance include:

- a. To establish and to manage Pharmacovigilance system in the respective Pharmaceutical Industry.
- b. To possess thorough understanding of drug safety profiles and to provide explanation regarding safety issues of drugs marketed by the concerned Pharmaceutical Industry.
- c. To act as the appointed person responsible for Pharmacovigilance and be available for contact 24 hours.

- d. To prepare all kinds of Pharmacovigilance reports.
- e. To promptly prepare and submit information on drug safety issues as requested by BPOM for risk-benefit assessment purpose.

Pharmaceutical Industry should be committed to building the capacity of the person responsible for Pharmacovigilance. Such commitment is to be reflected in their training plan, schedule, evaluation of trainings completed, and presence of sustainable procedures for the evaluation the person's capacity.

V.2. Pharmacovigilance Reporting

V.2.1. Spontaneous Adverse Events Reporting

A spontaneous reporting is a reporting of adverse events that are suspected to be caused by drugs, including vaccines, marketed by the Pharmaceutical Industry. The reporting is to be done by the Pharmaceutical Industry based on oral or written reports received from various credible sources, but it is neither part of any planned monitoring nor any study being undertaken.

The adverse events could either be serious or non-serious events. The criteria of serious adverse events comprise all medical occurrences associated with the use of drugs, including vaccines, that:

- a. results in death;
- b. is life threatening;
- c. requires hospitalization;
- d. prolongs hospitalization;
- e. causes permanent disability;
- f. results in congenital anomalies; and/or
- h. other significant medical occurrences.

V.2.1.1. Spontaneous Reporting of Adverse Events Associated With Uses of Drugs

The adverse events that should be monitored and reported upon in the spontaneous adverse events reporting comprise unexpected serious adverse events occurred both inside and outside the country, expected serious adverse events and unexpected non-serious adverse events occurred in the country.

The spontaneous reporting of serious adverse events, both expected and unexpected, must be promptly submitted to BPOM and not longer than 15 (fifteen) calendar days, in accordance with Appendix 1. Spontaneous reports of serious adverse events can be filed using the form attached in Appendix 2 and or the CIOMS form attached in Appendix 3.

Pharmaceutical Industry shall conduct the spontaneous reporting of unexpected non-serious adverse events occurred in the country in accordance with provisions set out in this Technical Guideline. If the case where no spontaneous adverse events report is received, the Pharmaceutical Industry should file a zero-report. The spontaneous reporting of such unexpected non-serious adverse events is to be filed once every 6 (six) months in the months of January and July in the tabular form prescribed in Appendix 4.

V.2.1.2. Spontaneous Reporting of Adverse Events Following Immunization (AEFI)

The AEFI that the Pharmaceutical Industry is required to report upon include unexpected serious AEFI occurred both inside and outside the country, expected serious AEFI occurred in the country and unexpected non-serious AEFI occurred in the country.

Reporting of serious AEFI that resulted in death must be done within 24 (twenty-four) hours in the next working day at the latest, filed as an initial report of the Pharmaceutical Industry since it becoming aware of the concerned information, and as a complete follow-up report in no later than 15 (fifteen) calendar days. Reports of other serious AEFI shall be filed within no more than 15 (fifteen) calendar days, in accordance with Appendix 5. The spontaneous reporting of serious AEFI can be submitted using the form attached in Appendix 6.

Pharmaceutical Industry is required to conduct spontaneous reporting of non-serious AEFI occurred in Indonesia, and that it is to be filed in accordance with the terms set forth in this Technical Guideline. In the case that the Pharmaceutical Industry receives no spontaneous reports of AEFI, it should file a zero report. The spontaneous reporting of non-serious AEFI is to be done once every 6 (six) months in the months of January and July presented in tabular form as prescribed in Appendix 7.

V.2.2. Periodic Safety Update Report (PSUR)

Periodic safety update report is safety surveillance and reporting activities carried out by Pharmaceutical Industry on their marketed drugs. PSUR is to be filed every 6 (six) months for the first 2 (two) years, and annually for the following 3 (three) years after the drug is approved for distribution in Indonesia.

Criteria of drugs that should be reported upon:

- a. Drugs with new active substances, including similar bio-therapeutic products.
- b. Other drugs as required by the Head of Agency.

The PSUR should at least contain the following information:

- a. Executive summary
- b. Introduction
- c. Distribution status
- d. Latest update on regulatory authority or Marketing Authorization Holder
Actions for safety reasons
- e. Changes to reference safety information
- f. Patients exposure data
- g. Individual case histories: line listings and summary tabulations (including
analysis of individual case histories, if necessary)
- h. Study results (if available)
- i. Other information (related to efficacy; critical updates on safety data)
- j. Overall safety information
- k. Conclusion

V.2.3. Post-marketing Safety Surveillance Reporting

The reporting of post-marketing safety surveillance must be carried out by the Pharmaceutical Industry holding distribution license for:

1. Drugs which distribution license approval specifies post-marketing safety surveillance as a condition; or
2. Certain drugs in distribution that are subject to post-marketing safety surveillance for the purpose of risk management planning, based on risks-benefit analyses and/or recommendation from a relevant team of experts.

Pharmaceutical Industry holding drug distribution license must report the surveillance results to the Head of Agency.

V.2.4. Published Case/Scientific Literature Reporting

Pharmaceutical Industry must report information on safety issues, which affect the benefit-risk profiles of their marketed drugs, appearing in publications or scientific literatures to the Head of Agency as soon as they learn about the existence of such publication or literature by attaching the publication/literature concerned.

V.2.5. Reporting of Actions Taken by Regulatory Authorities of Other Countries

Pharmaceutical Industry must promptly report information on actions taken by regulatory authorities of other countries in relation to safety issues, such as marketing authorization suspension or withdrawal, as well as product withdrawal. Preliminary reporting is to be filed within 24 hours since the information is received, on the next working day at the latest.

V.2.6. Reporting of Actions Taken by Marketing Authorization Holder in other countries

Pharmaceutical Industry in Indonesia must promptly report information on actions such as product withdrawal taken in relation to safety issues by Marketing Authorization Holders of the concerned drug in other countries. The reporting is to be done within 24 (twenty-four) hours since the information is received, on the next working day at the latest.

V.2.7. Reporting of Risk Management Plan Implementation

Reporting of outcomes from risk management plan undertaken by the Pharmaceutical Industry is to be carried out in accordance with the terms set herein.

VI. REPORTING PROCEDURES

Pharmaceutical Industry is to file the reports in accordance with the terms set forth in this Technical Guideline and should be addressed to:

Pharmacovigilance Center
c.q. Directorate of Distribution Control
Therapeutic Products and PKRT
National Agency of Drug and Food Control
Republik of Indonesia

Through several means:

- a. By post: Jl. Percetakan Negara No. 23, Jakarta Pusat, 10560
- b. Email: pv-center@pom.go.id
- c. Fax: +62-21-42883485
- d. Tel: +62-21-4244755 Ext. 111; 4244691 Ext. 1072

Upon receiving the reports BPOM will issue notification of submission within not more than 7 (seven) working days.

VII. DOCUMENTATION

The conduct of Pharmacovigilance must be supported by adequate documentation accessible for the BPOM officers during inspection. Documents that must be available include:

1. Curriculum vitae, job description and note of undertaken trainings of the persons responsible for Pharmacovigilance,
2. Standard Operational Procedures of all activities conducted,
3. Archives of individual cases of spontaneous reporting of both expected and unexpected serious adverse events and tables showing unexpected non-serious adverse events,
4. PSUR (if available),
5. Post-marketing safety surveillance reports,
6. Published case/scientific literature reports,
7. Reports of regulatory actions taken by regulatory authorities of other countries,
8. Reports of actions taken by marketing authorization holders in other countries, and/or
9. Reports on risk management plan implementation.

IX. Glossary

1. **Risk-benefit assessment** is examination of the risks and benefits of a certain drug.
2. **New chemical entity** is a chemical substance that has never been registered and licensed for distribution as an active drug ingredient in Indonesia.
3. **CIOMS** stands for Council for International Organizations of Medical Sciences.
4. **Dechallenge** is the end state of an adverse event after the use of the suspected drug is stopped.
5. **Effectiveness** is the measure of a drug's disease-fighting ability in an actual clinical situation.
6. **Adverse Drug Reaction (ADR)** is noxious and unintended response that occurs at doses normally used in humans for the prophylaxis, diagnosis, or therapy of disease, or for the modification of physiological function.
7. **Distribution license** is a form of registration approval for a drug to be distributed in Indonesia.
8. **Adverse Events** are untoward medical occurrences that may present during treatment with a medicine but which does not necessarily have a causal relationship with the medicine.
9. **Adverse Events Following Immunization (AEFI)** are medical occurrences that are related to an immunization, either in the form of vaccine reactions or side effects, toxicities, sensitivity reactions, pharmacological effects, or program errors, coincidental, injection reactions, or a causal relation that cannot be determined.
10. **Other important medical occurrences** are adverse events that physicians deemed as harmful to patient safety if not immediately addressed.
11. **Patient safety** is the avoidance, prevention and minimization of unwanted effects or harms caused by a health treatment process including use of drugs.

12. **Expectedness criteria** refer to ADRs that are predictable and already documented in the approved product information for use in Indonesia.
13. **Unexpectedness criteria** refer to ADRs that are unpredictable and not yet documented in the approved product information for use in Indonesia.
14. **Efficacy** is the ability of a drug to produce the intended therapeutic effects.
15. **Benefit** is the proven therapeutic good of a product, including patients' subjective assessment of its effect.
16. **New Drugs** are drugs containing new active ingredients or new additional ingredients, or having new forms of preparation/administration, or new indications, or new combinations that have never been approved in Indonesia.
17. **Risk** is the probability of harms that may be caused by a drug during clinical use, usually indicated in the form of percentage or ratio; the chances and odds of adverse events.
18. **Rechallenge** is the adverse events that reoccur after a drug is re-used or re-administered to patients who have previously recovered from side-effects associated with the same drug.
19. **Similar Biotherapeutic Product** is a biological product with similar safety profile, efficacy and quality claims to the already registered biological products.

X. Bibliography

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HEAD OF NATIONAL AGENCY OF DRUG AND FOOD CONTROL
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KUSTANTINAH