KINGDOM OF CAMBODIA
NATION RELIGION KING

MINISTRY OF HEALTH

DEPARTMENT OF DRUGS AND FOOD

ESSENTIAL DRUGS BUREAU

CAMBODIAN PHARMACOVIGILANCE CENTER

OPERATING GUIDELINES FOR

THE PHARMACOVIGILANCE ADVISORY COMMITTEE (PVAC)

Prepared by

PHARMACOVIGILANCE ADVISORY COMMITTEE

CAMBODIAN PHARMACOVIGILANCE CENTER

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Preface

The safe use of medicines by patients and by the population in general, is a high priority in the modern world. This implies to ensure that prescription rules are properly enforced, and that recommendations for proper use are adequately followed in order to maximize the therapeutic benefit while minimizing the risks inherent to any effective therapeutic agent.

Whilst all possible efforts should be made to prevent adverse drug reactions (ADR) to occur, it is also essential to have in place an effective Pharmacovigilance system designed to collect, compile and analyze the safety information received from ADR reports.

Pharmacovigilance Advisory Committee was created in the purpose of Pharmacovigilance System Operating in Cambodia. The committee will consist of senior officials from Ministry of Health (MOH), University of Health Sciences, National Hospitals, and National Center in Health Sector.

This guideline is designed to describe the committee member, their general and specific functions of Pharmacovigilance Advisory Committee which support to the development of Cambodian Pharmacovigilance Center. Additionally, this guideline mentions on the codes of conduct, role and responsibility of Cambodian Pharmacovigilance Center.

We expect this guideline to serve as general orientation and practical reference for use by Pharmacovigilance Advisory Committee that have to guide and support to the development of Cambodian Pharmacovigilance Center.

We would like to acknowledge the financial and technical support received from the Global Fund, World Health Organization and the Uppsala Monitoring Center (UMC) for producing this guideline.

Acknowledgement

For this *Operating Guidelines for The Advisory Committee*, we would like to extend our sincere thanks to the following persons:

HE. Chou Yin Sim	Secretary of state, Chair of PV advisory Committee.
HE. Or Vandin	Director general for Health.
Dr. Heng Bunkiet	Director of Department of Drugs and Food, Vice chair of PV advisory Committee.
HE. Lim Rathanak	Deputy Director of Department of Drugs and Food.
Dr. Chroeng Sokhan	President of Pharmacist Association of Cambodia, Vice chair of PV advisory Committee.
Mr. Ork Sophal	Deputy Director of Department of Drugs and Food.
Dr. Yang Daravuth	Deputy Director of Department of Drugs and Food.
Mr. Huot Sengthong	Deputy Director of Department of Drugs and Food.
Mrs. Nov Phalla	Deputy Director of Department of Drugs and Food.
Dr. Or Oudamrath	Chief of Essential Bureau, Member of PV advisory Committee.
Mr. Luk Saphy	Chief of Registration Bureau.
Mr. Sea thol	Deputy Chief of Essential Drugs Bureau and Deputy Chief of Secretariat of PV advisory Committee.
Mr. Cheap Thonvuthy	Deputy Chief of Essential Drugs Bureau and Chief of Cambodian Pharmacovigilance Center.
Mr. Chuon Vibol	Pharmacovigilance Technical Officer
Prof. Chheang Sena	Vice Dean at Faculty of Pharmacy, University of Health Sciences.
Dr. Sao Sokunna	Deputy Director of Department of Hospital.
Dent. Lay Vuthy	Vice Dean of Faculty of Dentistry, Member of PV advisory Committee.
Dr. Chhy Sokhom	Vice chief of CDC, Member of PV advisory Committee.
Dr. Bun Sreng	Deputy Director of CDC.
Ms. Vanchinsuren Lkhagvadorj	WHO Technical Officer on Pharmaceuticals at Department of Drugs and Food
Prof. Sten Olsson	Chief WHO Programme Officer at the Uppsala Monitoring Centre.
Dr. Jean C. Delumeau	Head of Pharmacovigilance Asia-Pacific, Bayer Healthcare, Vice-Chairperson of the PV Asia Network.

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DDF PHARMACOVIGILANCE UNIT WITH THE SUPPORT OF WHO CAMBODIA

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Cambodian Pharmacovigilance Center
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1. INTRODUCTION

This document (referred hereto as the *Operating guidelines for the Pharmacovigilance Advisory Committee, hereinafter referred to as "the Guidelines"*) shall guide operations of the *Pharmacovigilance Advisory Committee* (hereinafter referred to as "*the Committee"* and abbreviated as "*PVAC"*).

These Guidelines include procedures and decision criteria that the *Committee* will use in guiding its functions and in particular in respect of operations of the Pharmacovigilance Center (PVC) of the Ministry of Health (MoH), located at the Department of Drugs and Food (DDF).

The *Guidelines* shall be amended from time to time, after their approval, with the consultation of *the Committee.*

2. ESTABLISHMENT THE COMMITTEE

The Committee has been established in accordance with Ministerial Letter of Assignment dated 19 January 2010 with reference 023 with the purpose of guiding operations of the PV system in Cambodia.

3. COMPOSITION OF THE COMMITTEE:

The Committee will consist of senior officials from the Ministry of Health (MOH).

3.1. The Chairperson, Vice-chairperson(s) and other members of the Committee shall be appointed in accordance with a *Ministerial Letter of Assignment* to be issued by the Minister of Health from time to time as shall be deemed necessary.

3.2. Notwithstanding the generality of Clause 3.1 above, the Committee shall comprised of not more than 23 members preferably appointed from:

3.2.1. the MoH senior officials - responsible for the pharmaceutical sector (as the Chairperson);

3.2.2. the MoH/DDF senior officials and/or senior officials from the University of Health Sciences; faculties of medicines and/or pharmacy (as Vice-chairpersons); and

3.2.3. Other members of *the Committee* shall be drawn from:

a) National Hospitals; and
b) National Centers (medicines quality control, traditional medicines, maternal and child health, institutes of public health, HIV/AIDS, TB, Malaria, etc)

3.3. *The Committee* can invite, from time to time, technical staff/specialists of relevant disciplines to *Committee* meetings where critical decisions are to be made. Such invited staff/specialists shall have no voting rights.

3.4. *The Committee* may further invite other persons (not necessarily technical) in an advisory role as may be required, from time to time.

4. FUNCTIONS OF THE COMMITTEE

- ***General functions of the Committee***

The general functions of the Committee are to provide guidance and support to the development of the PVC.

- ***Specific functions of the Committee:***

To:

a) Advise on methods to be used to promote Adverse Drug Reactions (ADRs) reporting by relevant stakeholders;
b) Review, from time to time, reports and recommendations referred to the Committee by the PVC;
c) Assess safety issues from reports of serious Adverse Drug Reactions (ADRs), unexpected or toxic reactions submitted by the PVC;
d) Make decision on recommendations on causalities assessment of incidences submitted to the Committee by the PVC;
e) Recommend follow-up and investigation as necessary;
f) Submit Committee's decisions, conclusions and recommendations to the MoH;
g) Respond to MoH requests regarding the safety of any medicine; and
h) Conduct meetings of *the Committee* as further specified under Clause 5 below.

5. MEETINGS OF THE COMMITTEE:

5.1 Meetings of the Committee shall be convened by the Secretary on close consultation with the Chairperson.

5.2 Meetings of the Committee shall be chaired by the Chairperson or vice-chairperson in the absence of the Chairperson.

- ***Types of meetings***

5.3 The Committee will have two types of meetings:
a) Regular meetings; and
b) Special/Emergency meetings

Regular meetings

5.4 The Committee will hold regular (quarterly) meetings, the agenda of which will include a review of:

a) the performance of the PVC operations
b) reported ADRs reports referred by the PVC; and accordingly assess, where applicable, safety issues from serious ADR reports or toxic reactions; including an assessment of the causalities of the incidences
c) Any Other Business (as shall be proposed by Committee members)

5.5 The Secretariat will draw and make available to the Committee members a schedule of regular meetings indicating the dates and time for each meeting.

Special or Emergency meetings

5.6 The Committee will hold emergency meetings, the purpose of which will be to discuss emergency matters as they will be brought up by the Secretariat or any member of the Committee.

5.7 Special or Emergency meeting shall be called any time by the Chairperson and shall be chaired by the chairperson or vice-chairperson, in the absence of the chairperson.

- ***Notice of meetings***

5.8 Notice of meetings shall be sent by the Secretariat to all members of the Committee at least 10 working days prior to any regular meetings.

- ***Quorum for any Committee meetings***

5.9 **The quorum** at any meeting of the Committee shall be 50% of the members plus 1; one amongst them must be the Chairperson or vice-chairperson.

- ***Attendance to meetings***

5.10 Absence to a regular and/or any meeting of the Committee: by any member of the Committee shall be notified to the Secretariat if such members are unable to attend such a meeting(s).

5.11 Repeated absenteeism of a member without notice shall be reported by the Secretariat to Chairperson, with recommendation for appropriate action to be taken.

- ***Secretariat to Committee meetings***

5.12 The PVC, whose responsibilities are specified in Section 8 of these guidelines, shall constitute the Secretariat to the Committee.

5.13 Functions and responsibilities of the Secretariat to the Committee are provided under Schedule A of these guidelines.

5.14 The Secretary to the Committee shall maintain records and **minutes of all Committee meetings**, in a format prescribed and approved by the Committee; a sample of which is provided in Annex 1 of these guidelines.

6. DECISIONS OF THE COMMITTEE

6.1. Decisions of the committee shall be:

a) by consensus; or

b) failing consensus: by simple majority of members present by voting, and in the event of an equality of votes, the Chairperson shall have a casting vote in addition to his deliberative vote.

6.2. All decisions made by the Committee (by consensus of failing consensus as stipulated in Clauses 6.1 a) and b) above) shall be binding to all members present at any Committee meeting.

7. CODE OF CONDUCT:

- ***Confidentiality***

7.1 Members of the Committee and any staff of the PVC shall maintain, at all times, confidentiality of all matters brought to their attention, by virtue of them being members to the Committee or staff of the PVC.

- ***Impartiality***

7.2 Members of the Committee shall, to the best of their ability; exercise fairness to all matters brought to their attention for decision and shall act always to the best interest of the Kingdom of Cambodia.

- ***Transparency***

7.3 The Committee shall make decisions and recommendations to the MoH within a system which is fair, equitable, and transparent and which will always ensure the safety of patients.

7.4 Any matter submitted to the Committee for discussion, decision making and recommendation to the MoH must, therefore, demonstrate procedural fairness during the entire decision making process.

7.5 In the interest of transparency and patient safety, it is important that:

a) the manner in which decisions and recommendations are made, should be clearly and unambiguously stated in minutes of the Committee meeting; and

b) any decisions and recommendations, on the safety of medicines to patients, made by the Committee shall not, under any circumstances, be intended to favour a particular:

- patient
- pharmaceutical supplier/manufacturer or
- member of the Committee or PVC staff

7.6 In accordance to existing laws in Cambodia, it shall be illegal for any Committee member or PVC staff to accept any offer or service of significant value (as shall be determined by the Committee) in any form as an inducement to make decision in favor of a pharmaceutical company connected with any matter brought to the attention of the Committee for decision making.

7.7 Further to the above it shall be illegal for any Committee member or PVC staff to engage in other corrupt or fraudulent practices such as:

a) collusion with a pharmaceutical supplier/manufacturer:

- in forging or making false statements of any material or information submitted to the Committee
- by providing them with confidential information related to any matter related to or the decision making process of the Committee;

b) deliberately slowing down the process of decision making on the safety of a suspected pharmaceutical product in favour of a particular supplier;
c) providing to the MoH biased evaluation and recommendations on the safety of a pharmaceutical product;
d) not holding accountable a supplier or manufacturer of a suspected pharmaceutical product.
e) accepting bribes, kick backs or gifts (of a maximum value as shall be determined by the Committee from time to time); and

7.8 Further to Clauses 7.6 and 7.7 above: any Committee member or PV staff engaging in corrupt or fraudulent practices shall have disciplinary action taken against them as shall be deemed appropriate by the relevant authority.

7.9 Where, after appropriate investigations it is proved that any pharmaceutical company has engaged in corrupt or fraudulent practices that endangers the safety of patients, the Committee may recommend to the MoH:

a) the suspension or withdrawal of the registration of the company product; and

b) banning or blacklisting the company from trading in Cambodia for a period as shall to be recommended by the Committee to the Ministry of Health on a case to case basis.

7.10 Such supplier or manufacturer referred in Clauses 7.9 a) and b) shall be formerly informed of the circumstances leading to penalties specified under Clause 7.9 above.

- ***Conflict of interest***

7.11 any Committee member or staff of the PVC participating in any meeting of the Committee shall declare any interests that they may have on any matter brought before the Committee. Provided always that the Committee member or staff of the PVC with such vested interests shall:

a) declare such interests in the manner further prescribed and detailed under Schedule B of these guidelines; and

b) not take part or seek to influence in any way the Committee in its decision(s) where such conflict of interest is related to matter(s) under consideration by the Committee.

8. FUNCTIONS AND RESPONSIBILITIES OF THE PHARMACOVIGILANCE CENTER

8.1 Under the guidance of the PVAC the Center is, on the overall, responsible for monitoring the safety of medicines through:

8.1.1 Promoting the reporting of adverse reactions through education and training efforts to multiple stakeholders such as health facilities managers, public health program managers and staff, medical doctors, pharmacists, nurses, and patients/consumers.

8.1.2 Collecting case reports of adverse reactions through a simple, user-friendly, confidential system with provisions for feedback to reporters.

8.1.3 Collating, analyzing and evaluating patterns of adverse reactions through an identified agency or national expert committee.

8.1.4 Reporting incidents of lack of efficacy and suspected quality defects to relevant agencies and institutions for appropriate evaluation tests and advising relevant actions to take.

8.1.5 Disseminating the information on substandard and counterfeit medicines and how to prevent occurrence.

8.1.6 Working with the MOH to take regulatory action in response to findings.

8.1.7 Alerting prescribers and manufacturers to risks of adverse reactions for both old and new drugs.

8.1.8 Educating and informing patients of adverse reactions caused by specific medicines and actions that can be taken through a variety of advocacy channels.

8.1.9 Submitting reports to the WHO international ADR database (Vigibase) and contributing to the international drug safety efforts of more than 100 countries

8.1.10 Promoting rational and safe use of medicines through communication and education of ADRs and the prevention of medication errors and drug toxicities.

8.1.11 Building a library of literature and human resources (speakers' bureau or trainers) to maintain the growth and expansion of PV activities and to include PV topics into undergraduate health professional curriculum.

9. SCHEDULES

The Committee shall prescribe criteria and procedures in schedules annexed to these Guideline to govern the following decision making activities of the committee:

- Schedule A: Functions and responsibilities of the Secretariat
- Schedule B: Conflict of interest policy

SCHEDULE A: FUNCTIONS AND RESPONSIBILITIES OF THE SECRETARIAT TO THE PVAC

The Secretariat (staff of PV Center) shall be responsible for:

a) keeping in safe custody all ADR reports and drug related complaints

b) compiling a schedule of drug evaluation reports based on ADR reports and/or other reports from reliable sources.

c) ensuring the correctness of such reports prior to submitting the reports to the Committee;

d) submitting evaluation reports to the Committee at regular or special/emergence meetings of the Committee.

e) Copies of the evaluation reports shall be made available to Committee members on the date and time of the meeting.

f) The evaluation report, as approved by the Committee, shall be part of the minutes of meetings of the Committee.

g) maintaining minutes of the Committee meetings; particulars of which are as indicated in Annex 1 to this schedule.

ANNEX 1: FORMAT FOR MINUTES OF THE PVAC

TITLE: MINUTES OF THE (NUMBER) MEETING OF THE PVAC, HELD ON (DATE), AT (VENUE, AND TIME)

TYPE OF MEETING: REGULAR or SPECIAL/EMERGENCY
(Delete what is not applicable)

1. ATTENDANCE:

1.1 Present:

1.1.1 Names and position of members present

A list of members present shall be made and all members shall sign against their names to attest to their presence at the meeting. The list shall be part of the minutes of the meeting.

1.1.2 Names and position technical staff invited to the meeting, if any.

A list of technical staff or specialists invited to attend the meeting shall be made and all such invited staff/specialist shall sign against their names to attest to their presence at the meeting. The list shall be part of the minutes of the meeting.

1.2 Absent/apologies:

1.2.1 Names and position of members absent and reasons for their absence

1.2.2 Names and position of invited technical staff or specialists absent and reasons for their absence

2. Meeting proceedings

2.1 Summarize main points by agenda item, decisions of the Committee and actions to be taken

2.1.1 Agenda item 1:.....; e.g. members discussed and agreed by consensus to .....***Action:***....e.g. the Secretariat to.....

2.1.2 Agenda item 2:.....; e.g. members discussed and agreed by consensus to .....***Action:***....e.g. the Secretariat to.....

3. ANY OTHER BUSINESS

List and briefly describe Any Other Matters (A.O.B) considered by the Committee outside the announced agenda of the meeting.

4. ADJOURNMENT AND DATE FOR THE NEXT MEETING

Time of adjournment of the meeting and the proposed date for the next Committee meeting

5. SIGNATURES AND DATE

Spaces reserved for names and signatures of the Chairman and the Secretary to the Committee; who shall sign the corrected minutes after confirmation by the Committee at its next Committee meeting.

SCHEDULE - B: CONFLICT OF INTEREST POLICY

General Principles

a) People involved the assessment of the safety of medicines must operate in a fair, ethical, and transparent manner. This policy provides guidance in identifying and addressing potential, actual and apparent conflicts of interest. It is based on clear definitions of potential areas of concern, a duty to disclose, and outlines procedures for managing these conflicts as they arise.

b) The purpose of this policy is to ensure fairness in decision-making, to protect the reputation and integrity of the Ministry of Health in Cambodia, and to ensure broad public trust and confidence in the Government's decision-making mechanisms.

c) This policy is not intended to provide an exhaustive list of all instances of actual or potential conflicts of interest, but rather to articulate the ethical principles the Ministry of Health will follow in addressing such conflicts as they arise. Each situation will depend upon the facts of the case, but decisions will be governed by the guidelines set out in this policy.

Definitions

a) *Associated Person* includes a *member of the Committee or PVC staff's*:

- spouse, parent, minor child, domestic partner; or
- any organization, corporation or government in which he or she is serving as an officer, director, trustee, general partner or employee, and that receives or may receive benefits from having a healthcare product marketed in Cambodia.

b) Personally and substantially: to participate personally means to participate directly, including, for example, making a recommendation for a product safety etc . To participate substantially means that the *me*mber of the Committee and PVC staff's involvement is of significance to the matter.

c) Gifts shall mean any gratuity, favor, discount, entertainment, hospitality, loan, forbearance, or other item having monetary value. These include services as well as gifts of training, transportation, local travel, lodgings and meals, whether provided in-kind, by purchase of a ticket, payment in advance, or reimbursement after the expense has been incurred.

Conflicts of Interest

a) A conflict of interest arises when *a member of the Committee or PVC Staff* participates personally and substantially in an official capacity in any particular matter in which, to his or her knowledge, he or she or *an Associated Person* has

a financial [or other] interest, if the particular matter will have a direct and predictable effect on that interest. This includes situations:

- where *a member of the Committee or PVC Staff's* financial [or other] interests could affect the conduct of his or her duties and responsibilities with respect to their role in decisions related to drug safety;

- where *a member of the Committee or PVC Staff's* actions compromise or undermine the trust that the public places in the Ministry of Health, and

- in which *a member of the Committee or PVC Staff's* actions could reasonably impair or appear to impair the member of the Committee or PVC Staff's ability to act in the best interest of the people of Cambodia.

b) Conflicts of interest can be broken down into two general categories: direct and indirect.

i) Direct conflicts arise when *a member of the Committee or PVC Staff* or Associated Person has a direct interest in the decision and action in question. Examples of such interests include, but not limited to the following:

- persons taking actions that would affect their personal financial earnings or position in an organization or entity;

- a Committee member canvassing for a particular product for a company in which he or she has an active or inactive role.

ii) Indirect interests arise when *a member of the Committee or PVC Staff* or Associated Person stands to receive a diffuse benefit from the action in question. An example of such an interest would include a Committee member considering the safety of a product manufactured by a Cambodian manufacturer is likely to lead to benefit to the government through revenues earned or promoting local industry.

c) *A member of the Committee or PVC Staff's* shall not use their positions or information obtained during deliberation of the Committee or by virtue of them being members of the Committee or PVC staff to gain advantage for themselves (or Associated Persons).

Transparency and disclosure

a) All *members of the Committee or PVC Staff* have a duty to disclose the existence of potential or actual conflicts of interest (and the nature of such conflicts) whenever he or she becomes aware that a matter may involve an actual or potential conflict.

b) All *members of the Committee or PVC Staff* serving in the PVAC or PV Staff must complete and submit the attached "Declaration of Interest" form [Annex 2].

c) Disclosure statements shall be updated regularly, as the Committee may determine, and shall be available for inspection by a designated ethics official of the MoH.

d) Except for the purposes outlined above, statements stated in the "Declaration of Interest" form shall be confidential.

Procedure when a Conflict of Interest Arises

a) Conflicts of Interest shall be disclosed to the Secretary to the Committee.

b) The Secretary shall keep a record of Conflicts of Interest and shall be responsible for ensuring that relevant conflicts of interest, [and the actions taken to eliminate, reduce, and otherwise manage these conflicts], are disclosed prior to any decisions being made by the Committee.

c) It is the responsibility of each *member of the Committee or PVC Staff* to immediately disclose in writing to the Secretary the existence of any Conflict of Interest.

d) Material changes in declared interests must also be disclosed as they arise and become known.

e) *Members of the Committee or PVC Staff* are encouraged to consult with the Secretary for guidance if questions arise in the application of this policy.

f) It is the duty of the Secretary, to review disclosures submitted by *members of the Committee or PVC Staff* and to decide whether a Conflict of Interest exists and, if so, whether such *members of the Committee or PVC Staff* may participate in any discussion of the issue that has given rise to that conflict.

g) When it is determined that a Conflict of Interest exists, the *members of the Committee or PVC Staff* shall not participate in the matter brought for the Committee deliberation.

h) *Members of the Committee or PVC Staff* with a Conflict of Interest shall absent themselves without comment prior to any discussion or voting in respect of any matter related to the safety of medicines brought to the attention of the

Committee. However, if such persons must remain in meetings in order to fulfill their administrative responsibilities, they shall not participate in any discussion regarding the matter that has given rise to the Conflict of Interest.

i) The names of *members of the Committee or PVC Staff* with Conflicts of Interest, [as well as the extent of participation of that person in the relevant meeting] and the issue on which there is a notified Conflict shall be recorded in the minutes for that meeting.

j) Should a *members of the Committee or PVC Staff* be found to have a Conflict of Interest that has not been disclosed as required above, or the Secretary has reasonable cause to believe that a member of the Committee or PVC Staff has failed to disclose a Conflict of Interest, he/she will inform the *member of the Committee or PVC Staff* of the basis for such belief and provide him or her with the opportunity to explain the alleged failure to disclose. If, after hearing the response and making further investigations as may be warranted, the Secretary determines that the interested person has in fact failed to disclose a Conflict of Interest, it shall notify the Chairman of the Committee.

Gifts

All *members of the Committee or PVC Staff* and Associated Persons are prohibited from accepting Gifts of products and/or services in excess of a certain value (as shall be determined by the Committee from time to time) from persons or entities with interests that could be substantially affected by decision of the Committee.

Dissemination and Review of Policy

The Secretary shall distribute a copy of this policy to all *members of the Committee and PVC Staff* annually, along with a disclosure statement to be returned to the Secretary attesting that the *members of the Committee and PVC Staff* has received and read the Conflicts of Interest Policy. The Secretary shall retain these statements confidentially.

ANNEX 2: Conflict of interests declaration form

If you have no conflict to declare, please complete section 1 only OR
if you have a possible conflict to declare, complete section 2

SECTION 1

I, _____ have read the Conflict of Interest Policy." I wish to declare that I do not at present have and do not anticipate having any conflict of interests, as defined in the Conflict of Interest policy at the time of this filling this declaration form. If any conflict of interests arises, I shall notify the Secretary to the Committee in writing, immediately.

Name, signature_____

Date: _____

SECTION 2

I, _____have read the Conflict of Interest Policy. I wish to declare the following possible or actual conflicts of interests. (*Please describe each conflict of interests below)*.

_____

_____

_____

_____

_____

If any additional conflict of interests arises, I shall notify the Secretary to the Committee in writing, immediately.

*Name, signature*_____

Date:_____