Pharmacovigilance Monitoring System (PViMS) User Guide

Active Reporting of Adverse Events

Department of Health	**Revision Nº**	**1**
	Implementation Date	*August 2017*

About SIAPS

The goal of SIAPS is to assure the availability of quality pharmaceutical products and effective pharmaceutical services to achieve desired health outcomes. Toward this end, the SIAPS result areas include improving governance, building capacity for pharmaceutical management and services, addressing information needed for decision-making in the pharmaceutical sector, strengthening financing strategies and mechanisms to improve access to medicines, and increasing quality pharmaceutical services.

Recommended Citation

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CONTENTS

ABBREVIATIONS AND ACRONYMS

AE   adverse event
BID   twice daily
CTCAE   common terminology criteria for adverse events
DOH   Department of Health
ITIS   Integrated Tuberculosis Information System
MedDRA   Medical Dictionary for Regulatory Activities
PV   pharmacovigilance
PViMS   Pharmacovigilance Monitoring System
PVUM   *PViMS User Manual*
Q4H   every four hours
QD   daily
QID   four times daily
SIAPS   Systems for Improved Access to Pharmaceuticals and Services
SSTR   standard shorter treatment regimen
TB   tuberculosis
TID   three times daily
WHO   World Health Organization

MESSAGE

With the introduction of new medicines and novel regimens to treat drug-resistant tuberculosis (DR-TB) in the Philippines, the Department of Health (DOH) is committed to ensure the patient's safety and well-being through the guaranteed effectiveness of medicines and regimens. To support this effort, the National Tuberculosis Control Program (NTP) and the DOH-Pharmaceutical Division have taken the lead to adopt the web-based Pharmacovigilance Monitoring System (PViMS).

PViMS will help the NTP safeguard the rational use of medicines in treating DR-TB by facilitating the electronic reporting of suspected adverse reactions following treatment and the valuable analysis of data. This enables the early detection of potential safety and continuous enhancement of policies and standards.

The **PViMS User Guide: Active Reporting of Adverse Events**, developed jointly by the Department of Health and US Agency for International Development-funded Systems for Improved Access to Pharmaceuticals and Services Program, contains all essential information for the user to make full use of the system. This guide includes a description of the system functions and capabilities and step-by-step procedures for system access and use.

PViMS is also available to be used by other DOH programs, such as malaria, HIV/AIDS, immunization, family planning, maternal and child health and nutrition, to ensure not only patient safety for medicines being used in these programs, but all medicines in the Philippines as well.

Along with the continuous commitment of DOH and partners to promote health, this publication will contribute to the aim of ensuring medicines safety, efficacy and quality in the Philippines. The DOH believes that the use and adoption of this monitoring tool is necessary to strengthen the health system and to be aligned with the Philippine Health Agenda 2016-2022, with the battle cry *"All for Health towards Health for All."*

PAULYN JEAN B. ROSELL-UBIAL, MD, MPH, CESO II
Secretary of Health

DEFINITIONS

Adverse event (AE): Any untoward medical occurrence that may present during treatment with a pharmaceutical product, but which does not necessarily have a causal relationship with this treatment.

Cohort: Sub-group of the full condition group

Condition group: Primary population group to be analyzed defined by the condition

Encounter: Visit made by the patient to the health facility

MedDRA (Medical Dictionary for Regulatory Activities): Clinically validated, international medical terminology used by regulatory authorities and the regulated biopharmaceutical industry; the terminology is used through the entire regulatory process, from pre-marketing to post-marketing, and for data entry, retrieval, evaluation, and presentation; https://meddra.org

Pharmacovigilance (PV): Defined by WHO as "the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem"[1]

Serious adverse event: Any untoward medical occurrence that at any dose results in death, is life threatening, requires or prolongs patient hospitalization, results in persistent disability/incapacity, or is a congenital anomaly/birth defect[2]; "life threatening" refers to an event in which the patient was at risk of death at the time of the event—it does not refer to an event that hypothetically might have caused death if it were more severe

Signal: Reported information on a possible causal relationship between an AE and a drug, the relationship being unknown or incompletely documented previously; usually more than a single report is required to generate a signal, depending upon the seriousness of the event and the quality of the information

RATIONALE AND PURPOSE

Pharmacovigilance (PV) is an integral part of the health care system critical in ensuring patient safety and overall public health. The Department of Health (DOH) is in the process of strengthening the PV system for its public health programs. A tool that streamlines and simplifies data collection, data analysis, signal detection, and causality assessment is necessary for effective PV. As part of this initiative, the DOH-Pharmaceutical Division has adopted the Pharmacovigilance Monitoring System (PViMS), a web-based surveillance tool developed by the USAID-funded Systems for Improved Access to Pharmaceuticals and Services (SIAPS) Program. Using PViMS will contribute to strengthening the PV system and improving patient safety by monitoring medicine safety data and identifying signals from different adverse event (AE) reports.

The user guide primarily serves as a reference in reporting an AE through PViMS. It also serves to guide reporters and investigators in completing a correct and accurate AE report. This guide outlines the key data needed, starting from the initial alert to the completion of an AE report in PViMS.

TARGET AUDIENCE

The primary users of this guide are implementers directly involved in health service delivery under DOH public health programs. This includes staff from the health-facility, provincial, and regional levels involved in PV data collection and reporting activities. Managers and supervisors at the national and regional levels may use this guide as a basis for planning, monitoring, and evaluating PV activities.

The user guide outlines only the data needed to complete an AE report in PViMS. The criteria used to determine which AEs to report are described in the manuals of procedures and/or implementing guidelines for the respective health programs. For example, the level of medicine safety monitoring for the National Tuberculosis Program is described in the National TB Program Manual of Procedure[3] and PMDT Implementing Guidelines.[4]

This guide only focuses on encoding data in PViMS and does not cover the entire functionality and navigation within the information system. For the complete PViMS software guide, refer to the PViMS user manual.[5]

SUMMARY OF PROCEDURES

1) File and complete the initial data required for reporting AEs in PViMS

   a) Enter patient information; for TB patients, the following data will come from the Integrated Tuberculosis Information System (ITIS)

      - Last Name
      - First Name
      - Date of Birth
      - Facility
      - Sex
      - Medical Record Number
      - Country of Birth
      - Condition Group
      - Condition Group MedDRA Terminology
      - Condition Start Date

   b) Enter required AE data

      - MedDRA Terminology
      - Event Description (as stated by patient or reporter)
      - Onset Date
      - Full Name of Reporter

   c) Enter all medications (treatment regimen, concomittant, ancillary) taken by the patient at the time of the event. For regimens containing bedaquiline, also encode medications taken two weeks before the event. For TB patients, treatment regimen data will come from ITIS.

      - Medication (generic name)
      - Start Date

2) Encode supplementary data related to the AE for causality assessment

   a) Encode the supplementary patient information

      - Cohort
      - Cohort Enrollment Date

   b) Encode the supplemental AE data

      - Resolution Date
      - Treatment of Reaction

- Was AE attributed to one or more drugs?
- Outcome
- Was the event reported to national PV?
- Is the event serious?
- Seriousness
- Severity Grading Scale
- Severity Grade
- Date of Report
- Type of Reporter
- Reporter Contact Number
- Remarks

c) Enter supplemental patient medication data

- Medication
- Start Date
- End Date
- Dose
- Dose Unit
- Dose Frequency
- Route
- Frequency in days per week
- Still on Medication?
- Indication Type
- Actions
- Reason for Stopping
- Clinician action taken with regard to medicine if related to AE
- Effect of Dechallenge (D) & Rechallenge (R)
- Remarks

d) Enter the patient condition, including any concurrent medical disorder

- MedDRA Terminology
- Condition Start Date
- Condition Outcome
- Condition Outcome Date
- Treatment Outcome
- Condition Ongoing

e) Enter tests and procedures relevant to the event: (1) Baseline, (2) Most recent to the onset of the event, (3) Onset of the event, and (4) Monitoring test results after the event

- Test or Procedure
- Test Date

- Test Result (Coded)
- Test Result (Value)
- Reference Range–Lower Limit
- Reference Range–Upper Limit

f) Enter other patient information at the time of the event in the Encounter:

- Height
- Weight
- Pregnancy (for females of reproductive age only)

    o Date of last mentrual period (of reproductive age and if pregnant)
    o Estimated gestation in weeks (of reproductive age and if pregnant)

1. FILE AND COMPLETE THE INITIAL DATA REQUIRED FOR REPORTING AN ADVERSE EVENT

This section outlines the steps and data required for developing a valid, initial report of a new AE in PViMS.

Reminders

- The data mentioned in this section are only the minimum required data for an AE report to be valid. If supplementary data are available, it is recommended to encode it in PViMS during the initial reporting.

- If any of the data mentioned in this section is missing when filing the initial report, then it is not a valid report.

- ITIS users should not add new patients through PViMS under any circumstances—new patients should only be added through ITIS. This is done by sending patient data from ITIS to PViMS (refer to annex A to transfer data from ITIS to PViMS).

Steps

1) Enter the PViMS website (https://pvims.doh.gov.ph) by using the PViMS credentials provided to you.

   If you don't have a PViMS user account, refer to annex B to request a new user account.

   If you forgot your PViMS credentials, refer to annex C to request a new password or existing user name details.

2) Search for the patient with the occurrence of an AE in PViMS. For detailed instructions, refer to *PViMS User Manual* (hereafter referred to as PVUM) Section 4.1.1 Search for Patients.

3) Create or view the patient record in PViMS.

   a) If the patient record is not found, create a new patient record in PViMS.

      For non-ITIS users, refer to the detailed instructions in PVUM Section 4.1.4 Add a New Patient.

      For ITIS users, refer to annex A in this document to transfer data from ITIS to PViMS to create a new patient record. After following the instructions in annex A, skip step 4 and go to step 5.

b) If the patient record is found, go to the patient's record in PViMS. For detailed instructions on how to view the patient's record, refer to PVUM Section 4.1.3 View an Existing Patient; skip step 4 and go to step 5.

4) Enter the following required patient data in PViMS. This data is required for the initial AE report. For patients who have existing records in ITIS, these data are transferred to PViMS from ITIS (step 3).

- Last Name: encode the first letter of the last name only; for example, if the last name is Cruz, encode the letter C

- First Name: encode the first letter of the first name; for example, if the first name is Juan, encode the letter J

- Date of Birth: if the exact month and/or day are unknown, encode June 30 and subtract current age from the current year

- Facility where the patient is being treated

- Sex

- Medical Record Number, which is a unique identifier given by the public health program; for the TB program, this is the TB case number

- Country of Birth

- Patient's Condition: select the patient's predefined primary condition group from the drop-down list (e.g., TB, HIV, Malaria)

- MedDRA Terms: select the corresponding MedDRA term for the primary condition from the drop-down list (e.g., Pulmonary tuberculosis, Multidrug-resistant tuberculosis, Miliary tuberculosis)

- Start Date of the patient's primary condition; use the date of the confirmatory laboratory test; if the exact date is unknown, use June 30

Tip: steps 5 and 6 can be done interchangeably

5) Encode all medications taken by patient at the time the AE occurred, including, but not limited to, the treatment regimen and concomitant and ancillary medications. For regimens containing bedaquiline, also encode medications taken two weeks before the event.

a) For patients with existing records in ITIS, each treatment regimen medicine is transferred to PViMS, including the dosage combination, after the user prompt (step 3).

b) For detailed instructions on adding patient medications, refer to PVUM Section 4.2.4.6 Add a Patient Medication; the following data are required for the initial patient medication report:

- Medication: select the generic name of the patient's medicine from the drop-down list; if the generic name is not among the selection, refer to annex D to report missing data in the drop-down list

- Start Date is the date the patient took the drug and the AE/serious AE occurred

> **Note**: For ITIS users, if the treatment regimen medicine entries in ITIS are incorrect or incomplete, add or edit the treatment regimen medicine data in ITIS and refer to annex A to update the treatment regimen data in PViMS.

6) Enter at least the required data for the AE details when filing the initial report.

   a) MedDRA Terminology: code the AE, always selecting the lowest-level term for term type; for term results, choose the lowest-level term that mostly accurately reflects the verbatim or AE description.

   For example, the event description is "increased SGOT"

   When looking for the MedDRA term, search first for the exact event description if there is an actual match in MedDRA. If a match is not found, try different variations (e.g., SGOT increased, SGOT increase, SGOT) until the mostly accurate MedDRA term that reflects the verbatim or AE description is found.

   > **Note**: Coding allows the reduction and standardization of a large amount of information into a form that can be more easily handled during data processing, reporting, analysis, and communication.

   b) Event Description (as stated by the patient or reporter): narrative in the patient form or the verbatim account of the event as described by the patient or reporter, whichever is more precise; narratives should be written in Filipino or English only.

   c) Onset Date: date the event started.

   d) Full Name of Reporter: the reporter is the facility-level staff who detected the AE. The reporter maybe different from the person encoding the data.

   This data field is essential as the reporter will be the primary source of information in the health facility during the investigation or causality assessment. The full name of the reporter must be written as, for example, Juan Cruz, Juan dela Cruz, Juan Cruz III.

> **Tips**
>
> To edit any entry, refer to PVUM Section 4.2.4
>
> To delete an entry, refer to PVUM Section 4.5

2. ENCODE THE SUPPLEMENTARY DATA RELATED TO THE ADVERSE EVENT FOR CAUSALITY ASSESSMENT

This section outlines the necessary steps and information for providing supplementary data to the initial AE report.

Reminders

- Reporters or investigators should encode any supplementary data as it becomes available.
- Supplementary PV data for completing an AE report varies for each public health program.

Steps

1) Enter the PViMS website (https://pvims.doh.gov.ph), using the PViMS credentials provided to you.

   If you forget your PViMS credentials refer to annex C for detailed instructions on how to recover your account.

2) View the patient's record in PViMS. For detailed instructions, refer to PVUM Section 4.1.3 View an Existing Patient

Tip: steps 3 to 7 can be done interchangeably.

3) Enter the supplementary data for the reported medications related to the event. Do not create a new adverse event. For detailed instructions, refer to PVUM Section 4.2.4.7 Edit an Existing Patient Medication.

   - Brand Name

   - End Date: the date the patient stopped taking the medicine

   - Dose: number of units

   - Dose Unit (e.g., mg, mEq, IU): if the dose unit is not among the selection in the drop-down list, refer to annex D to report missing data in the drop-down list

   - Dose Frequency: number of times per day the dose is administered (e.g., QD, BID, TID, QID, Q4H, etc.)

   - Route: path by which a drug is taken into the body (oral, intravenous, intramuscular, etc.)

   - Frequency: number of days the drug is administered per week (e.g., 7 days, 1 day)

- Still on Medication: as all the medicines to be reported in the initial report are taken by the patient, enter Yes

- Type of Indication: crucial in conducting a causality assessment. Three indication types:

  o Primary: select if the medicines are taken to treat the current condition to which the patient belongs
  o Concomittant: select Pre-existing condition if the medicines are taken for a pre-existing condition prior to diagnosis of the current condition to which the patient belongs
  o Treat AE: select if the medicines taken are used to treat an AE

- Clinician action taken with regard to medicine if related to AE: encode only if action was taken on the medicine because of the AE

  o Dose not changed: drug is continued with the same dose
  o Dose reduced: drug is continued with reduction of dose
  o Drug interrupted: drug is temporarily on hold
  o Drug withdrawn: drug is stopped or discontinued
  o Not applicable: no action taken regarding the drug in relation to the AE

- Effect of Dechallenge (D) & Rechallenge (R): select the effect of the medicine to the patient with regard to stopping (dechallenge) and restarting (rechallenge) the medicine.

  o If medicine dechallenge is performed, do the following:

    a) In the medicine data field, change Still on Medication to No
    b) Enter the End Date when the medicine was ended
    c) Answer only the options in the Effect of Dechallenge (D) & Rechallenge (R) data field that starts with D

  o If medicine rechallenge is performed, do the following:

    a) Create a new entry for the medicine with all of the required data fields for patient medications
    b) Answer only the options in the Effect of Dechallenge (D) & Rechallenge (R) data field that starts with R

- Remarks: any additional notes on the drug that are not captured by the data fields above. If drug withdrawn is selected in the data field Clinician action taken with regard to medicine if related to AE, write the name of the replacement drug, if any, in the remarks.

4) Enter the supplementary data on the AE.

- Resolution Date: date the event was resolved or stabilized

- Treatment of Reaction: select among the options (No Treatment, Non-medical Treatment, Medical Treatment, Dialysis, Surgery, Unknown) to indicate how the reaction was treated

- Was the AE attributed to one or more drugs? Select Yes or No

- Outcome: select among the options (Resolved, Resolved with sequelae, Fatal, Resolving, Not Resolved, Unknown) to indicate the outcome of the reaction

  o When the outcome is Fatal, ensure that Condition Outcome and Condition Outcome Date are updated; for detailed instructions on how to update the condition outcome, refer to PVUM Section 4.2.4.3 Edit an Existing Patient Condition.

- Is the event serious? Select Yes or No; the event is classified as serious if it meets the WHO definitions[6]

- Seriousness: select the seriousness of the AE.

  o In the event of Death, provide the:

    - Date of Death
    - Autopsy Done, if applicable

  o In the event of initial or prolonged hospitalization, provide the:

    - Admission Date: date the patient was admitted to the hospital
    - Discharge Date: date the patient was discharged from the hospital

- Severity Grading Scale: select the grading scale used by the public health program to which the patient belongs (e.g., CTCAE, DAIDS, WHO)

  o For TB patients, select the CTCAE Grading Scale; for more information about CTCAE, refer to reference 7

- Severity Grade: select the grade from the drop-down list (e.g., Grade 1, Grade 2, Grade 3, Grade 4, or Grade 5) . The Severity Grade description for CTCAE is described in reference 7

- Was the event reported to the national PV center?: Select yes because data recorded in PViMS can automatically be accessed by the national PV authorities.

- Date of Report: date the event was reported to the facility

- Type of Reporter: select the reporter's profession from among the list (physician, pharmacist, other health professional, lawyer, consumer, or non-health professional)

- Reporter Contact Number; contact number of the reporter or the facility

- Remarks: narrative or additional information on the AE, including, but not limited to, how the AE was managed at the health facility

5) Encode the patient's comorbidities (e.g., diabetes). For detailed instructions on adding a patient's condition, refer to PVUM Section 4.2.4.1 Add a Patient Condition. The following are supplementary data:

- MedDRA Terminology: always select the lowest-level term for term type; in the term results, choose the lowest-level term that mostly accurately reflects the verbatim or AE description

- Condition Start Date: start date of the patient's diagnosis; for a concurrent medical disorder, if the exact month and/or date are unknown, enter June 30

- Condition Outcome: permanent outcome of the patient's condition as concluded by the treating physician (i.e., Fatal, Not Recovered/Not Resolved, Recovered/Resolved, Recovered/Resolved with Sequelae, Recovering/Resolving, Unknown)

- Condition Outcome Date: date of the outcome of the patient's condition

- Treatment Outcome: outcome of the treatment as concluded by the treating physician (i.e., cured, died, lost to follow-up, not evaluated, treatment completed, treatment failed)

- Condition Ongoing: select yes if the medical condition is still ongoing; select no if the medical condition has an outcome

> **Tips**
>
> The Condition Outcome, Condition Outcome Date, and Treatment Outcome are not immediately required prior to the causality assessment. These may be entered as described in section 3 of this document.
>
> If the patient's condition data are not all available at the same time, the MedDRA Terminology and Condition Start Date can be added initially and the patient condition record can be edited when the data becomes available. For detailed instructions on how to update patient conditions, refer to PVUM Section 4.2.4.3 Edit an Existing Patient Condition.

6) Enter all event-related tests and procedures performed on the patient; for detailed instructions, refer to PVUM Section 4.2.4.8 Add a Test or Procedure. Enter the (a) baseline tests, (b) most recent tests prior to onset of the event, (c) tests on the onset of the event, and (d) tests to monitor the patient after the event; the following are required:

- Test or Procedure: name of the test performed on the patient; if the test or procedure is not in the drop-down list, refer to annex D

- Test Date: date the test or procedure was performed

- Test Result (Coded): enter data if the test result is coded (i.e., positive, negative, abnormal, normal)

  For example, HBsAG has a Test Result (Coded) of either seropositive or seronegative; for AFB Smear, the Smear Result can be Positive or Negative; the quantification result should be written in the Test Result (Value) data field.

  If the Test Result (Coded) is not in the drop-down list, refer to annex D.

- Test Result (Value): enter data if the test result value is numerical; for AFB Smear, list the Quantification (i.e., Scanty, 1+, 2+, 3+) in the Test Result (Value)

- Reference Range – Lower Limit: if the Test Result (Value) is numerical, enter the lower-level limit of the Test Result (Value)

- Reference Range – Upper Limit: if the Test Result (Value) is numerical, enter the upper-level limit of the Test Result (Value)

- Test Unit: the unit of the Test Result (Value); if the Test Unit is not in the drop-down list, refer to annex D

- Remarks: enter any data, remarks, or notes on the tests that were not captured by the fields listed above

7) To create a new encounter for a patient, go to PVUM Section 4.1.7.5 Add an Encounter

- Encounter Type; select the default value Not Set
- Priority: select the default value Not Set
- Encounter Date: date should be the same as the Onset Date of the AE

  Note: Encounter Type and Priority are required when creating an Encounter, but is critical only for patients under clinical research.

8) To add details or edit the AE encounter, refer to PVUM Section 4.2.3 Edit Encounter Information. The following are supplemental data:

- Height: found in the Medical Details tab, this is the height of the patient in centimeters (cm) at the time of the event; if the height was not taken on the exact date of the event, the most recent height before the onset of the AE should be recorded

- Weight: found in the Medical Details tab, this is the weight of the patient in kilograms (kg) at the time of the event; if the weight was not taken on the exact date of the event, the most recent weight before onset of the AE should be recorded

- Pregnancy Status: only for female patients of reproductive age

- Date of Last Menstrual Period: for female patients of reproductive age, including those who are pregnant

- Estimated Gestation (Weeks): for pregnant patients

9) Assign or update the patient cohort by selecting from the pre-defined cohort list when adding new patients; this step is not mandatory for public health programs with no assigned cohorts

- Treatment Cohort: group where the patient is categorized based on treatment regimen (e.g., TB program: SSTR, bedaquiline)

- Cohort Enrollment Date: date the patient was categorized under the specific cohort; Cohort Enrollment Date is the same as the confirmatory laboratory test of the patient's condition

  If the patient is already assigned to another cohort and there are changes, de-enroll the patient first before assigning a new cohort.

3. Cohort De-enrollment Date: date of the last dose of the previous regimen; de-enrolled just means the date on which they are no longer a part of this cohort. It is for analysis purposes only.

For Your Information

- Supplemental data for reporting AEs may vary for public health programs. The data listed here are the minimum health data required by the national regulatory authority.

- The data fields in PViMS not mentioned in this user guide are for surveillance of patients under clinical research. They are not part of PV data collected for public health programs.

- For more guidance on the implementation of active drug safety monitoring under the TB program, refer to the framework for implementation.[8]

UPDATE PATIENT TREATMENT AND CONDITION OUTCOMES

Even after the causal relationship between the drug and AE has been determined, patient condition and treatment outcomes should be updated in PViMS for accurate analysis of the PV data. Analysis of PV data is done per cohort or per condition.

Steps

- Update patient condition outcomes: for relevant instructions, refer to PVUM Section 4.2.4.3 Edit an Existing Patient Condition

  o Condition Outcome: permanent outcome of the patient condition as concluded by the treating physician (i.e., Fatal, Not Recovered/Not Resolved, Recovered/Resolved, Recovered/Resolved with Sequelae, Recovering/Resolving, Unknown)
  o Condition Outcome Date: date of the outcome of the patient's condition
  o Treatment Outcome: outcome of the treatment as concluded by the treating physician (i.e., Cured, Died, Lost to Follow-up, Not Evaluated, Treatment Completed, Treatment Failed)
  o Condition Ongoing: select Yes if the medical condition is still ongoing; select No if the medical condition has an outcome

- Update the patient cohort: this step is not mandatory for public health programs that have no cohorts

  o Cohort: group where the patient was categorized based on treatment regimen (e.g., TB program: SSTR, bedaquiline)
  o Cohort Enrollment Date: date the patient was categorized under the specific cohort; Cohort Enrollment Date is the same as the confirmatory laboratory test of the patient's condition

    When the patient is already assigned to another cohort and there are changes, de-enroll the patient first before assigning a new cohort.

- Cohort De-enrollment Date: date of last dose of the previous regimen

REFERENCES

1) WHO. Importance of Pharmacovigilance: Safety Monitoring of Medicinal Products; p. 7. 2002; http://apps.who.int/medicinedocs/pdf/s4893e/s4893e.pdf

2) International Conference on Harmonisation. Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting, E2D; p. 1. Step 4 version, November 2003; https://www.ich.org/fileadmin/Public_Web_Site/ICH_Products/Guidelines/Efficacy/E2D/Step4/E2D_Guideline.pdf

3) National TB Program Manual of Procedure, 5th edition; http://www.ntp.doh.gov.ph/downloads/publications/NTP_MOP_5th_Edition.pdf

4) NTP PMDT Implementing Guidelines; http://www.ntp.doh.gov.ph/downloads/policies/ao2016-0040.pdf

5) Pharmacovigilance Monitoring System (PViMS) User Manual; https://pvims.doh.gov.ph

6) WHO. Safety Monitoring of Medicinal Products: Guidelines for Setting Up and Running a Pharmacovigilance Centre. Uppsala, Sweden; 2000; http://apps.who.int/medicinedocs/en/d/Jh2934e/

7) US Department of Health and Human Services. Common Terminology Criteria for Adverse Events (CTCAE), version 4.03; June 2010; https://evs.nci.nih.gov/ftp1/CTCAE/CTCAE_4.03_2010-06-14_QuickReference_5x7.pdf

8) WHO. Active drug safety monitoring and management (aDSM): Framework for implementation. 2015; http://www.who.int/tb/publications/aDSM/en/

ANNEX A. TRANSFERRING DATA FROM ITIS TO PVIMS

1) Login to the PViMS website (https://pvims.doh.gov.ph) using the PViMS credentials provided to you

2) On another browser tab, enter the ITIS website (https://itis.doh.gov.ph) using the ITIS credentials provided to you.

3) After successfully entering your user name and password in the login page, the system will welcome and redirect you to the ITIS home page. In the ITIS home page, click the Case Management button.
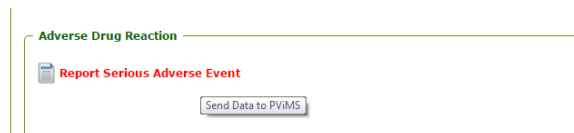

Case Management

4) On the Case Management page, search for the patient who had an occurrence of an AE and then open the patient record.

5) Click the Case Holding tab on the patient's page in ITIS who had an occurrence of an AE.

6) In the Case Holding tab, scroll down below until you see the Report Serious Adverse Event link.

7) A pop-up window will appear listing the data to be sent to PViMS. Examine the data and then click the Send to PViMS button when set. If necessary, edit the patient data prior to moving to the next step.


8) A pop-up window will appear, asking if you want to send the previously listed data from ITIS to PViMS. Click OK to send the data to PViMS. Click Cancel to go back to the previous screen.

9) After clicking the OK button, ITIS will automatically send data to PViMS.

10) After ITIS successfully sends data to PViMS, ITIS will display a link to PViMS. Click this link to redirect you to the patient's page.
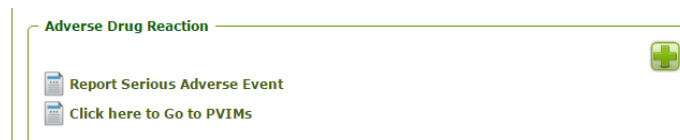
ANNEX B. REQUESTING A NEW USER ACCOUNT

Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

June 27, 2017

DEPARTMENT MEMORANDUM
No. 2017 - **0272**

FOR: **SECRETARY OF HEALTH OF AUTONOMOUS REGION IN MUSLIM MINDANAO, ALL DOH REGIONAL DIRECTORS AND MEDICAL CENTER CHIEFS/DIRECTORS OF HOSPITALS WITH PROGRAMMATIC MANAGEMENT OF DRUG-RESISTANT (PMDT) FACILITIES**

SUBJECT: **Issuance of Pharmacovigilance Monitoring System (PViMS) User Account**

The World Health Organization (WHO) describes pharmacovigilance (PV) as the science and activities relating to the detection, assessment, understanding and prevention of adverse effects or any other medicine-related problem. The definition of the WHO also covers new innovator compounds under clinical trials to ascertain efficacy and safety. The approval of every innovator compound is premised on the principle that the benefit from use of the new medicine must outweigh the risk of the disease/s it is intended to cure, as well as the harm that may arise from its use. As the population studied during the pre-approval phase is relatively limited, PV integrates a post-marketing surveillance phase for all newly approved innovator medicines to further establish safety in a wider population base.

The Department of Health (DOH) through the Pharmaceutical Division (PD) under the Office for Policy and Health Systems (OPHS) adopted a web-based application Pharmacovigilance Monitoring System (PViMS) through the USAID/Philippines' Systems for Improved Access to Pharmaceuticals and Services (SIAPS). The PViMS will help the DOH to ensure the patient's safety for medicines being distributed to health facilities.

In line with this, the DOH will issue set of guidelines in the implementation of PViMS for reporting adverse drug events following administration of medicines under NTP.

SCOPE:
This issuance applies to the Department of Health (DOH), the National Tuberculosis Control Program (NTP), Health Facilities provided with DOH medicines.
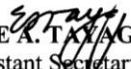
GENERAL GUIDELINES:

    A. The DOH-PD as the lead office in rolling out the monitoring of adverse drug events following administration of medicines being distributed by the DOH shall also be the lead office in implementing the utilization of PViMS.

    B. The PD in coordination with the Knowledge Management & Information Technology Services (KMITS) shall continue the provision of technical support to all identified health facilities as the PViMS is rolled out.

SPECIFIC GUIDELINES:

    A. Issuance of Users Account:

        1. The NTP or the Public Health Program Manager shall identify all the reporting facilities and personnel who are authorized to access and use the PViMS system. The list of reporting and personnel shall be submitted to DOH-PD for the issuance of usernames and passwords.

        2. The DOH-PD shall release the assigned usernames and passwords to the reporting facilities' authorized staff or the user access owner

        3. The DOH-PD shall assign at least one (1) username and password for each reporting facility.

    B. Suspension, Termination and Lifting of User's Account

    Upon recommendation and endorsement of the NTP or Public Health Programs to the DOH-PD, the users' accounts may be suspended, terminated or lifted accordingly.

For strict compliance.

By the Authority of the Secretary of Health

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ANNEX C: REQUESTING A PASSWORD OR EXISTING USERNAME DETAILS

Purpose

This policy defines procedures for health facilities on requesting existing user account details in PViMS.

Scope

Any staff within the public health network that has an existing username and password in PViMS.

Definitions and Acronyms

Username: an identification used by a person with access to a computer, network, or online service

Password: a string of characters that allows access to a computer, interface, or system

System administrator: a person who manages the operation of a computer system

Procedures

1) Confirm if the PViMS username and password details are missing:

   - Search the email where the PViMS user account was requested
   - Search in email the PViMS user account and password sent by the PViMS administrator

2) Send an e-mail to the PViMS system administrator at dohpvphp@gmail.com to request your PViMS username and password with the subject "Request for user account details".

3) Wait for the response of the PViMS system administrator for the user account details.

4) Test your PViMS user account upon receipt.

5) Confirm to the system administrator that you have successfully logged in at PViMS by replying to the same email thread.

ANNEX D. REPORTING MISSING DATA IN THE DROP-DOWN LIST

Purpose

This policy defines guidelines for health facilities on requesting additional data selections in PViMS.

Scope

Any staff within the public health network that are assigned to report AEs through PViMS

Definition

System administrator: a person who manages the operation of a computer system

Procedures

1) Any PViMS user can request additional selection data in the following drop-down lists:

   - Medications (generic name)
   - Tests and Procedures
   - Test Result (Coded)
   - Test Unit

2) Confirm that the data are not in the above-mentioned PViMS drop-down lists.

3) Send an email to the PViMS service desk at dohpvphp@gmail.com with the subject "Request for adding data in drop-down list".

4) Specify the following information in your email:

   - Drop-down data-field name (Medications, Tests and Procedures, Test Result (Coded) or Test Unit)
   - Drop-down list name you are requesting to be added

5) Wait for the confirmation from the PViMS system administrator that the data have been added.

6) Confirm to the PViMS system administrator that the data has been added.

ANNEX E. LIST OF CONTRIBUTORS

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