Republic of the Philippines
Department of Health
OFFICE OF THE SECRETARY

JUN 02 2020

ADMINISTRATIVE ORDER
No. 2020 - 0025

SUBJECT: Policy and Guidelines on the Implementation of Active Drug Safety Monitoring and Management (aDSM) of the National Tuberculosis Control Program (NTP)

I. RATIONALE

The Disease Prevention and Control Bureau - National Tuberculosis Control Program (DPCB-NTP) has been implementing the use of Standard Shorter Treatment Regimen (SSTR) which reduces the treatment duration for patients with multi-drug resistant tuberculosis (MDR-TB) from eighteen (18) months to nine (9) months. Moreover, the DPCB-NTP has already introduced the use of new anti-TB drugs such as Bedaquiline (BDQ) and Delamanid (DLM), and repurposed drugs such as Linezolid (LZD), Clofazimine (CFZ), and Imipenem/Cilastatin (IPM/CLS), for patients with drug-resistant TB (DR-TB) in the country. These two (2) new interventions in TB management require active surveillance as part of pharmacovigilance for patients under MDR-TB and extensively Drug-Resistant TB (XDR-TB) treatment. In 2015, the Active Tuberculosis Drug-Safety Monitoring and Management (aDSM) Framework for Implementation of the World Health Organization (WHO) recommended immediate action for countries to adopt aDSM to complement the aforementioned interventions of the TB program.

In the WHO aDSM Framework for Implementation Manual (2015), WHO defines aDSM as the active and systematic, clinical, and laboratory assessment of patients while on treatment using new anti-TB drugs, novel MDR-TB regimens or XDR-TB regimens to detect, manage, and report suspected or confirmed drug toxicities. aDSM aims to reduce risks from drug-related harms in patients on new anti-TB drugs, novel treatment regimens, or XDR-TB regimens, to generate standardized aDSM data to enhance the detection of new signals, and to formulate policy and guideline updates on TB treatment. This is distinct from existing mechanism of spontaneous reporting system implemented by the National Pharmacovigilance Center (NPvC) – of the Food and Drug Administration (FDA).

The Pharmacovigilance Monitoring System (PViMS) is a web-based monitoring tool, which enables the implementation of active surveillance activities in low- and middle-income countries (LMICs) by addressing the entire data collection, data analysis, and reporting process.

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This allows decision makers to identify potential adverse events related to medicine use, and consequently implement decisions for improving patient safety. The Department of Health - Pharmaceutical Division (DOH-PD), which is in charge of monitoring medicine distribution under public health programs (PHPs) in different health facilities, has included pharmacovigilance of PHPs in its operations, as authorized by the FDA. In 2017, the DOH-PD has adopted the PViMS for adverse events observed mainly in patients with DR-TB receiving new anti-TB drugs with shorter regimen.

The aDSM implementation is an integral component of the comprehensive package of TB services that will be provided to all patients with TB using a new anti-TB drug, a repurposed drug, or a new regimen. This is aligned with the goal of the "Universal Health Care Act" to provide comprehensive quality and cost-effective health care services for all. This is also one of the key strategies to support the realization of the goal of the *FOUR*mula One Plus, to achieve better health outcomes, particularly for patients with TB.

II. OBJECTIVES

This Administrative Order (AO) aims to:

A. General:

Provide policies and guidelines on the implementation of aDSM for all patients with TB using a new anti-TB drug, a repurposed drug, or a new regimen.

B. Specific:

1. Define the roles and responsibilities of DOH offices, stakeholders, and partners involved in the implementation of the aDSM system in the country;
2. Provide guidelines for the establishment of partnerships with Local Government Units (LGUs) and Hospitals in implementing the aDSM in the country; and,
3. Standardize data collection and processing of Adverse Events (AE) reports from the implementing health facilities to further assess the safety of a new drug, a repurposed drug or a new regimen for DR-TB.

III. SCOPE AND COVERAGE

This Order shall apply to all health facilities, both public and private, and health professionals providing treatment to all patients with TB using a new anti-TB drug, a repurposed drug or a new regimen, the DOH concerned offices, Centers for Health Development (CHDs), Ministry of Health – Bangsamoro Autonomous Region in Muslim Mindanao (MOH-BARMM), LGUs, and other stakeholders involved in aDSM.

IV. DEFINITION OF TERMS

A. **Adverse Drug Reaction (ADR)** – refers to a response to a medicine that is noxious and unintended, and which occurs at doses normally used in humans.

B. **Adverse Event (AE)** – refers to 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.

C. **Adverse Event of Special Interest (AESI)**– refers to an AE documented to have occurred during clinical trials and for which the monitoring program is specifically sensitized to report regardless of its seriousness, severity or causal relationship to the TB treatment. (Refer to Annex A)

D. **Causality Assessment (CA)** – refers to the evaluation of the likelihood that a TB medicine was the causative agent of an observed adverse event.

E. **Expected Serious Adverse Event (Expected SAE)** – refers to serious adverse events (SAEs) or reaction which occurred in a human study participant from previous researches or investigations. This can also be considered as any SAEs listed in the drug literature.

F. **Extensively Drug-Resistant Tuberculosis (XDR-TB)** – refers to a form of TB caused by *Mycobacterium tuberculosis* that is resistant in vitro to the effects of any fluoroquinolone (e.g., levofloxacin, moxifloxacin) and second line injectable agent (e.g., amikacin), in addition to at least both isoniazid and rifampicin.

G. **Individual Case Safety Report (ICSR)** – refers to a document that contains information describing the adverse event/s related to the administration of one or more medicinal products to an individual patient.

H. **Intermediate Package** – refers to the level of monitoring in aDSM that includes serious adverse events as well as adverse events of special interest.

I. **Multi Drug-Resistant Tuberculosis (MDR-TB)** – refers to a form of TB caused by *Mycobacterium tuberculosis* that is resistant in vitro to the effects of at least both isoniazid and rifampicin.

J. **Pharmacovigilance** – refers to the science and activities relating to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problem.

K. **Public Health Programs (PHPs)** – refers to programs initiated by the DOH involving, among others, the promotion of access to essential medicines in the public sector to address priority diseases.

L. **Repurposed Drug** – refers to a drug that is recommended by WHO for use in the treatment of TB but was approved by a regulatory authority for the treatment of other infectious diseases.

M. **Serious Adverse Event (SAE)** – refers to an AE that is life threatening or results in death, requires hospitalization or prolongation of hospitalization, results in persistent or significant disability or incapacity, or a congenital anomaly. AEs that do not immediately result in one of these outcomes, but which require an intervention to prevent a serious outcome, are included.

N. **Signal** – refers to reported information on a possible causal relationship between an adverse event and a drug in which the relationship was unknown or incompletely documented previously. Usually more than a single report is required to generate signal, depending upon the seriousness of the event and the quality of the information.

O. **Unexpected Serious Adverse Event (Unexpected SAE)** – refers to serious adverse events or reaction, the nature and severity of which is not consistent with domestic labeling or market authorization, or unexpected from the characteristics of the drug.

V. GENERAL GUIDELINES

A. The DOH, through the PD, shall create a National aDSM Coordination Committee (NaCC) to oversee and support the implementation of aDSM in health facilities providing treatment for TB.

B. The DOH-PD and the DPCB-NTP shall adopt and implement aDSM following the intermediate package level of monitoring for all patients with TB using a new anti-TB drug, a repurposed drug, or a new regimen.

C. All health facilities providing treatment for TB shall adopt the prescribed mechanism for reporting SAEs and AESIs experienced by patients with utmost confidentiality by using the assigned TB-registration number instead of the patient's name.

D. All healthcare professionals (e.g., physicians, nurses, and midwives) providing TB services shall be trained on TB disease and AE management to ensure safety of the patients as stated in the Administrative Order 2016-0040 also known as the "Revised Policies and Guidelines on the Implementation of the Programmatic Management of Drug-Resistant TB (PMDT)." (*IV. Implementing Guidelines (IG)*)

E. The healthcare professional shall promptly identify and properly manage AEs in order to deliver the best possible patient care based on the approved or acceptable clinical pathways of the DPCB-NTP.

F. The DOH-PD in coordination with DPCB-NTP and Health Promotion and Communication Service (HPCS) shall initiate strategic communications and awareness campaigns on aDSM to ensure momentous support which will create a sustainable change.

G. The CHDs, MOH-BARMM, LGUs, health facilities providing treatment for TB, and other stakeholders shall implement the prescribed communications and awareness campaigns on aDSM.

VI. SPECIFIC GUIDELINES

A. Composition of the National aDSM Coordination Committee (NaCC) and Operational Procedures for Meetings

1. The NaCC shall be composed of relevant stakeholders from the DOH-PD, DOH-NTP, and FDA.

2. The NaCC shall be supported by ad hoc members from other DOH offices such as but not limited to the following offices: Epidemiology Bureau (EB), HPCS, and the Knowledge Management and Information Technology Service (KMITS).

3. The NaCC shall convene at least twice a year for the program implementation review (PIR).

4. The NaCC members shall fill out a form declaring their conflict of interest before each meeting and submit this to the secretariat. Members with potential conflict of interest can exercise partial participation in the deliberation on a specific topic but will not be allowed to vote on the matter.

5. The decision and/or recommendation of the NaCC shall be based on unanimous agreement by the group.

6. The NaCC shall be supported by staff from DOH-PD who shall serve as the secretariat.

B. Management of Adverse Events (AEs)

1. Detection of AEs

All healthcare professionals (e.g., physicians, nurses, midwives) providing treatment for TB shall detect and manage adverse events through active and systematic baseline and follow-up clinical, laboratory, and diagnostic monitoring.

2. Clinical Management of AEs

a. Upon detection of AEs, the physician-in-charge shall conduct a thorough assessment of the patient for proper clinical management.
b. Appropriate laboratory or diagnostic test/s when indicated shall be requested to obtain objective evidence of the AEs.
c. The reported AEs as identified shall be managed with reference to the Programmatic Management of Drug-Resistant TB (PMDT) implementation guidelines.
d. The patient shall be referred to a specialist, when necessary, for further evaluation and management.

3. Recording and Reporting of SAEs and AESIs

a. All SAEs and AESIs shall be recorded using the prescribed NTP forms (refer to Annex B) and reported to DOH-PD through PViMS or any prescribed web-based reporting system within two (2) working days (refer to Annex C).
b. In health facilities where PViMS or any prescribed web-based reporting system is not available, the appropriate form (refer to Annex D) shall be filled out. The form shall be submitted to the CHD or MOH - BARMM NTP Coordinator, copy furnished the National Drug Policy Compliance Officer (NDPCO) designate at the CHD or MOH-BARMM. The NDPCO designate shall encode the data through PViMS or any prescribed web-based reporting system within two (2) working days.
c. Adverse events (AEs) that are suspected to be due to a quality defect of an anti-TB drug shall be reported immediately to the FDA. Appropriate number of samples shall be submitted to confirm the quality of medicine as mandated under FDA Circular No. 2018-013 (Risk Management Plan for Drug Establishments) and its amendments. The healthcare professionals may consult the DOH-hired pharmacists for any other quality issues with the medicine.

4. Causality Assessment (CA) of SAEs and AESIs

a. The DOH-PD shall determine the relationship between the anti-TB drug/s and event/s by conducting causality assessment of reported SAEs and AESIs using

the WHO – Uppsala Monitoring Center (UMC) system for standardized case causality assessment. Other causality assessment methods may also be used, when necessary.

b. DOH-hired Pharmacists shall collect additional data that are essential in conducting causality assessment. The health facilities providing TB services shall allow the DOH-hired Pharmacists to validate AE reports and collect supplemental data as required by the DOH-PD, in accordance with Republic Act No. 10173 also known as the "Data Privacy Act of 2012" Section 13.e.
c. SAEs and AESIs needing expert opinion as determined by DOH-PD shall be compiled and reported to an aDSM Causality Assessment Committee (aCAC). Such cases shall then be reviewed and assessed by the Committee to come up with a recommended causality assessment (Refer to Annex E and F for the composition/qualifications and operational procedures for meetings).
d. The DOH-PD shall submit individual case report of SAEs and AESIs to FDA not later than fifteen (15) days after the completion of causality assessment through an electronic system. The FDA shall then transmit the data to WHO- UMC.
e. The DOH-PD shall transmit the data to WHO Global aDSM Database developed by the WHO/Global TB Programme (GTB) and WHO/Special Programme for Research and Training in Tropical Diseases through PViMS or any other prescribed web-based reporting system.

5. **Feedback**

a. The DOH-PD shall send an acknowledgement response to the reporter for every report received.
b. After the report of adverse event has been assessed, the DOH-PD shall provide feedback only on the unexpected SAEs. Expected SAEs and AESIs shall not require feedback unless significant issues have not been addressed to minimize the occurrence of such events.
c. An active line of communication (e.g., telephone, mobile phone, facsimile, social media private messages or electronic mail) shall be maintained at all times for the purpose of feedback reporting within and between all levels of health delivery system (national, regional, provincial/city, and municipal).

C. Risk Minimization

1. The FDA shall review all reports of adverse events related to aDSM.

Unknown or undocumented information between adverse event and drug shall constitute a signal.

Confirmation of a signal, through scientific and literature review or by any other means, shall warrant an investigation and potential regulatory action.

4. The FDA shall provide the necessary information to the NaCC, DOH-PD, and NTP.

D. Risk Communication

1. The DOH-PD, in coordination with NTP, HPCS, and FDA, shall develop a comprehensive aDSM risk communication plan, which shall be disseminated to relevant stakeholders.

2. The DOH-Media Relations Unit (MRU), in coordination with DOH-PD, Office of the Chief of Staff (OCS), and FDA, shall prepare and disseminate press releases and facilitate press conferences, as deemed necessary.

VII. PROGRAM MONITORING AND EVALUATION

A. The DOH-PD shall be the lead, in coordination with the DPCB-NTP and its CHDs and MOH-BARMM counterparts, in monitoring the implementation of aDSM every (6) months and shall have the authority to check the documents relevant to aDSM.

B. The DOH-PD, through the CHDs and MOH-BARMM, shall validate the integrity and transparency of the records of the health facilities.

C. The program shall be evaluated at least once every three (3) years or as often as deemed necessary by the DOH-PD.

D. Monitoring and Evaluation shall be performed by utilizing a monitoring tool approved by the NaCC and aligned with the DOH Monitoring and Evaluation guidelines.

VIII. ROLES AND RESPONSIBILITIES

A. DOH Central Offices

1. The **DOH-Pharmaceutical Division (DOH-PD)** shall:

   a. Lead the implementation of this order and serve as the focal unit for aDSM;
   b. Lead in monitoring the implementation of aDSM every six (6) months;
   c. Allot funds in support to the implementation of aDSM;
   d. Conduct causality assessment and submit case reports/assessments of SAEs and AESIs to the FDA, which shall then transmit these data to the WHO-UMC;
   e. Transmit the data on SAEs and AESIs to the Global aDSM database;
   f. Create an aCAC which shall be composed of external experts;
   g. Coordinate with aCAC for causality assessment of complicated cases and signals detection;
   h. Maintain a database of all reported SAEs and AESIs from health facilities

providing treatment for TB;

i. Coordinate with the NDPCO designates in the CHDs and MOH-BARMM for any supplemental data needed for the assessment of reported AEs;
j. Develop and cascade the Manual of Procedures (MOP) for aDSM, duly consulted with stakeholders and approved by the head of the Health Regulation Team (HRT);
k. Serve as the secretariat of the NaCC and aCAC;
l. Provide feedback in a timely manner to stakeholders, as necessary;
m. Maintain and cascade the use of PViMS or any prescribed web-based reporting system; and,
n. Develop and oversee the implementation of the Risk Communication Plan (RCP) for aDSM, in coordination with HPCS and DPCB-NTP.

2. The **National aDSM Coordination Committee (NaCC)** shall:

a. Oversee aDSM implementation and its alignment to the DOH National Objectives Plan;
b. Develop policies, guidelines, and MOPs on aDSM as well as the DPCB-NTP implementing guidelines; and,
c. Provide recommendation and technical assistance for the implementation of aDSM.

3. The **aDSM Causality Assessment Committee (aCAC)** shall:

a. Review and assess causality assessment reports needing expert opinion;
b. Assess any signal detected and develop necessary risk minimization measures; and,
c. Assist in the finalization of AE reports, especially those that require expert opinion.

4. The **DPCB through NTP** shall:

a. Formulate and/or modify TB treatment policies based on the recommendations from national/local authorities and/or international organizations;
b. Participate in case investigations of suspected AEs, when necessary;
c. Coordinate aDSM activities with the NTP program managers both at the national and regional (i.e., CHD and MOH-BARMM) levels;
d. Train healthcare professionals on the clinical management of AEs; and,
e. Participate in the monitoring and evaluation of the aDSM implementation, in coordination with DOH-PD and FDA.

5. The **Health Promotion and Communication Service (HPCS)** shall:

   a. Develop a national risk communication plan (RCP) for aDSM and cascade this to the regions to develop their regional risk communication plans;
   b. Monitor and evaluate the implementation of the RCP by the Health Education and Promotion Officers (HEPOs) in their respective regions; and,
   c. Provide feedback to the national office and recommend actions, as necessary.

B. The **Food and Drug Administration (FDA)** shall:

1. Investigate signal/s detected;
2. Respond on events referred by the DOH-PD, through the Center for Drug Regulation and Research (CDRR)-Pharmacovigilance Unit, for further investigation and regulatory action;
3. Provide feedback on referred cases of DOH-PD on AEs;
4. Provide technical assistance to DOH-PD and aCAC regarding pharmacovigilance issues;
5. Coordinate with HPCS, MRU, and DOH-PD in preparing and developing key messages for advisories and press statement;
6. Submit reported adverse drug events to the WHO-UMC; and,
7. Participate in the monitoring and evaluation of the aDSM implementation, in coordination with the DOH-PD and DPCB-NTP.

C. The **CHDs** and **MOH-BARMM** *through the* **NDPCO** and the **NTP Coordinator** shall:

1. Oversee the aDSM implementation in the regions;
2. Ensure dissemination of and compliance to aDSM policies and standards;
3. Collect supplemental data needed for causality assessment, when necessary;
4. Coordinate with the LGUs and health facilities requiring additional data and management of cases;
5. Ensure proper encoding of health facility data into PViMS or any prescribed web- based reporting system;
6. Participate in case investigations of suspected AEs;
7. Monitor and evaluate the aDSM implementation in the regions; and,
8. Cascade the Risk and Communication Plan for aDSM to the LGUs.

D. The **LGUs (Provincial/City Health Offices),** through the designated TB Coordinator shall:

1. Implement the aDSM guidelines within the province/municipality/city;
2. Ensure dissemination of and compliance to aDSM policies and standards;
3. Ensure recording and reporting of SAEs and AESIs by health facilities providing treatment for TB;
4. Participate in case investigations of suspected AEs;

5. Support administrative and logistical requirements needed for aDSM implementation, including capacity building for healthcare professionals;
6. Provide logistical support (medical assistance, etc.) for patients requiring clinical management of SAEs;
7. Authorize CHD and MOH-BARMM staff to validate AE reports and collect supplemental data as required by the DOH-PD; and,
8. Monitor and evaluate the aDSM implementation.

E. The **Health Facilities Providing Treatment for TB** shall:

1. Identify promptly the occurrence of any AE and manage properly all identified AEs;
2. Collect and encode the reports of SAEs and AESIs into the PViMS or any prescribed web-based reporting system;
3. Report all SAEs and AESIs to the FDA Pharmacovigilance Unit and National Pharmacovigilance Center, using the approved prescribed reporting forms and systems;
4. Coordinate with the CHD or MOH-BARMM, through the NDCPO designates or assigned DOH-hired Pharmacists, for the encoding of reports to PViMS or any prescribed web-based reporting system;
5. Analyze all data generated from implementation of aDSM at the facility level;
6. Educate patients to monitor their clinical condition following administration of new drugs, repurposed drugs or new regimen and to promptly report any AEs to healthcare professionals;
7. Maintain integrity and transparency of records and make data available to both the DOH and FDA; and,
8. Participate in the case investigation of suspected AEs.

IX. FUNDING

Each agency identified in this Order shall endeavor to include in their budget the funds necessary for its implementation.

X. REPEALING CLAUSE

All rules, issuances, orders, or parts thereof, contrary to or inconsistent with this Administrative Order are hereby repealed or amended accordingly. All other issuances not otherwise affected shall remain valid and in effect.

XI. EFFECTIVITY

This Administrative Order shall take effect after fifteen (15) days following its publication in a newspaper of general circulation and upon filing with the University of the Philippines Law Center of three (3) certified copies of this Order.

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Secretary of Health

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ANNEX A
Adverse Events of Special Interest (AESI)

a. Acute kidney injury (acute renal failure)
b. Hepatitis (defined as increases in alanine aminotransferase (ALT) or aspartate aminotransferase (AST) ≥5x the upper limit of normal (ULN), or increases in ALT or AST ≥3x ULN with clinical manifestations, or increases in ALT or AST ≥3x ULN with concomitant increase in bilirubin ≥1.5x ULN)
c. Hypokalemia
d. Myelosuppression (manifested as anemia, thrombocytopenia, neutropenia, or leucopenia)
e. Optic nerve disorder (optic neuritis), or retinopathy
f. Ototoxicity (hearing impairment, hearing loss of any degree)
g. Pancreatitis
h. Peripheral neuropathy (paresthesia)
i. Prolonged QT interval (Fridericia correction) of >500 ms or >60 ms increased from baseline
j. Psychiatric disorders and central nervous system toxicity (e.g. depression, psychosis, suicidal intention, seizures)

Reference:

World Health Organization. (2015). *Active tuberculosis drug-safety monitoring and management (aDSM): Framework for implementation* (No. WHO/HTM/TB/2015.28). World Health Organization.

ANNEX B
Form 4 TB Treatment Card

National TB Control Program (NTP)

Form 4. TB/ IPT Treatment Card

Treatment Facility (Name & Region):	Treatment Site/ Partner (Name, Type & City/ Province): [ ] FB [ ] CB	Date Transferred (MM/DD/YYYY):
Diagnosis: [ ] (Active) TB [ ] Latent TB Infection	Treatment Regimen: [ ] IPT [ ] Category 1 [ ] Category 1a [ ] Short [ ] Conventional specify, _____	

Full Name (SURNAME, First & Middle):	TB Case Number:	Date of Registration (MM/DD/YYYY):	Treatment Start Date (MM/DD/YYYY):

Age:	Sex (M/F):	Date of Birth (MM/DD/YYYY):	Height (cm):	Initial Weight (kg):	Civil Status:	PhilHealth Number:	Social Class: [ ] Indigent

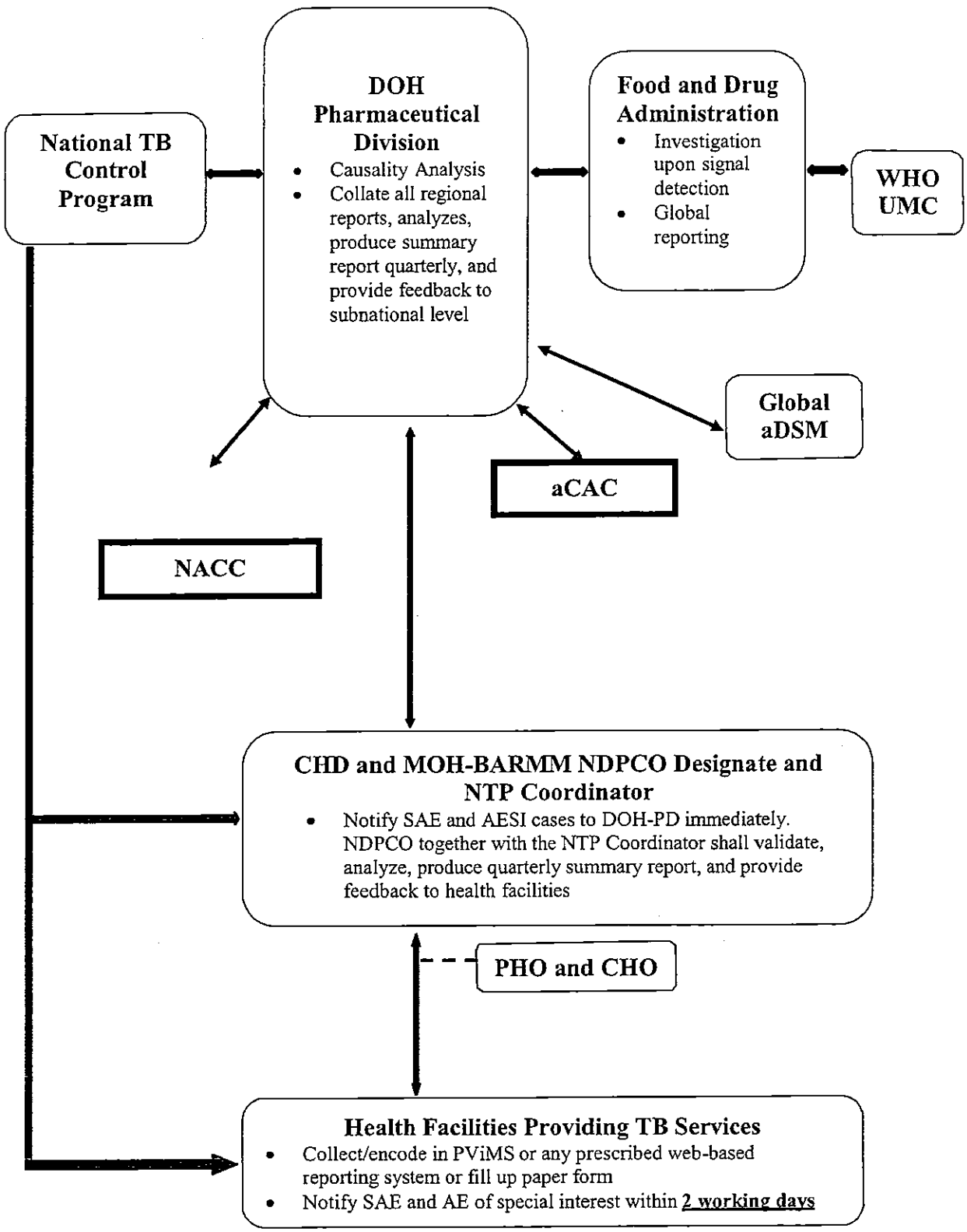
Permanent Address (House No., Sheet, Barangay, City/ Municipality, Province, Region & Zip Code):	Contact Numbers/ E-mail Address:
Current Address (House No., Sheet, Barangay, City/ Municipality, Province, Region & Zip Code):	Person to notify in case of emergency, relationship & contact information:

If (Active) TB,	History of TB Treatment: [ ] None [ ] FLD Only [ ] FLD and SLD
Anatomical Site: [ ] Pulmonary [ ] Extra-pulmonary	Date Treatment Started / Treatment Unit / Anti-TB Drugs & Duration / Outcome
TB Bacteriological Status: [ ] Bacteriologically-confirmed [ ] Clinically-diagnosed	earliest
DR-TB Bacteriological Stat [ ] BC RR-TB [ ] BC MDR-TB [ ] BC XDR-TB	
[ ] CD MDR-TB [ ] Other DR-TB	
Registration Group: [ ] New [ ] Relapse [ ] Treatment After Failure	
[ ] Treatment After Loss to F/-Up	latest
[ ] Previous Treatment Outcome Unknown [ ] Others	
Risk Factors for TB: [ ] None [ ] Contact of a Confirmed TB/ DR-TB Case	
[ ] PLH(V with S/S Suggestive of TB	
[ ] Other: _____	

Treatment Outcome: [ ] Cured [ ] Completed [ ] Failed [ ] Died [ ] Lost to Follow-up [ ] Excluded Reason:	Outcome Date (MM/DD/YYYY):

ANNEX C

Process Flow for Reporting and Feedback SAEs and AESIs



ANNEX D

Reporting Form for Adverse Drug Reactions (Food and Drug Administration)

SUSPECTED ADVERSE REACTIONS FORM v 5 (4/2012)
"Saving Lives Through Vigilant Reporting"
**FIELDS MUST BE COMPLETED.*

For FDA use only
AER No. 2012-0001
Date received: _____

All reports are confidential.

PATIENT'S PARTICULARS

*Patient's Name or Initials_____ * Sex: ☐ Male ☐ Female Weight _____Kg Height (cm) _____

Address or Contact Number: _____ *Age_____ Date of Birth (mm/dd/yr)_____

Medical History/Admitting Diagnosis: _____ Ethnic group: ☐ Filipino ☐ Chinese ☐ Caucasian

Any Known Allergy: ☐ No ☐Yes, Specify:_____ Pregnancy Status: ___ No

Hospital/facility , if admitted:_____ ___ Yes (1st, 2nd, 3rd trimester)

DETAILS OF THE ADVERSE REACTION

Date of onset:_____: ____am, ____pm

Do you consider the reaction to be serious? ☐ Yes, if yes indicate why: ☐ No

Describe the reaction, including pertinent laboratory data:

- ☐ Patient died due to reaction
- ☐ Involved or prolonged in-patient hospitalization
- ☐ Life threatening
- ☐ Involved persistent or significant disability
- ☐ Congenital anomaly in the newborn
- ☐ Other outcome, please give details:

Can this be due to Medication Error? ☐ No
☐ Yes, if yes, which type:
___Prescribing
___Transcription
___Dispensing
___Administration

Can the adverse reaction be due to :

1. Product quality defect ___No ___Yes, Specify, encircle: color change ; caking; powdering ; counterfeit; odor change; defective container; contaminants; separation of components; undissolved suspension/powder
2. Therapeutic failure: ___No ___Yes, Specify, encircle: antimicrobial resistance, drug interaction, poor compliance, counterfeit, expired; improper storage; under-dosing, inappropriate medication; inappropriate route of administration; excipients/preservatives

*Suspected drug product(s) Indicate brand name	Daily Dose	Route	Date started	Date stopped	Reason (s) for using the product (Indication)	Manufacturer and Batch/Lot #

List all other drug/s taken at the same time and/or 3 months before. If none, check box. ☐ No Other drug/s taken

Brand name of the drug	Daily Dose	Route	Date started	Date stopped	Reason/s for using the drug	Manufacturer and Batch & Lot No.

MANAGEMENT OF ADVERSE REACTION

Was treatment given? ☐ No ☐ Yes (If yes, please specify): _____

Outcome:
☐ Recovered (Date of recovery):_____ ☐ Unrecovered Other diseases: ____liver ____renal ____HPN
☐ Fatal (Date of death):_____ ☐ Unknown ____Diabetes ____CVS ___Endocrine ___Cancer

Sequela/e: (any permanent complications or injuries as a result of the ADR) Re-challenge? ☐ Yes Result_____
☐ Yes (Please specify)_____ ☐ No ☐ Unknown ☐ No

REPORTER'S PARTICULARS

*Printed Name of Reporter: _____ *Contact no:_____

Signature of reporter: _____ Email address: _____

Date reported (mm/dd/yr): _____ *Profession: __MD ___RPh ___RN ___Patient ___Dentist ___other
*Facility: ___Clinic ___Trial site _____Other

FDA Philippines — Food and Drug Administration

National Pharmacovigilance Center
"Saving Lives Through Vigilant Reporting"
Send completed form to: ADR Unit, FDA, Civic Drive, Filinvest Estate, Alabang, Muntinlupa ,1781.
Or fax to: (02) 807-85-11, c/o The ADR Unit. Send sample, if any, of suspect drug for analysis.
Website: www.fda.gov.ph

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ANNEX E

aDSM Causality Assessment Committee Meeting Operational Procedures

1. The Committee shall convene regularly (once every quarter) during the first year of its creation and as needed thereafter when there is a call to review and oversee the causality assessment of reported SAEs and AESIs.

2. The Committee members shall fill out a form declaring their conflict of interest before each meeting and submit this to the secretariat. Members with potentially conflicting interest can exercise partial participation in the deliberation on a specific topic but will not be allowed to vote on the matter.

3. The decision and/or recommendation of the NaCC shall be based on the unanimous agreement by the group.

ANNEX F

aDSM Causality Assessment Committee Qualification and Membership

The Pharmaceutical Division, Program Implementation Monitoring Unit (PIMU), shall serve as its **secretariat**.

A. The Committee shall have a representation of the following:

1. Professional affiliation which includes but not limited to the field of academia, medical professional, clinical practice, research institutes, and government bodies including public health departments, and regulatory authorities.
2. Major areas of expertise, which include but not limited to respiratory disease, cardiovascular disease, immunological disease, research, biologics, and drug safety.

B. Conditions for committee membership are the following:

1. The committee members shall be appointed on an ad hoc basis to serve with compensation as indicated in the terms of reference.
2. All nominations for new committee member, as well as renewal and discontinuation of appointments, must be approved by the Secretary of Health.
3. The Committee may request upon department, bureaus, office, agency, or other instrumentality of the government and local government units for assistance as the circumstance and exigencies may require.
4. In addition, prior to the confirmation by the DOH of their appointment as committee member, nominees shall be required to sign a confidentiality undertaking. The signed confidentiality undertaking shall be maintained by the DOH-Pharmaceutical Division. All deliberations of the committee are considered confidential and shall not be disclosed to the public by any member.
5. (stipulate the declaration of COI)

C. The members of the committee may be terminated for any of the following reasons:

1. Lack of professionalism involving but not limited to, breach of the confidentiality, misuse of position for personal gain, bribery and misinterpretation.
2. Undeclared Conflict of Interest (COI) to the roles and objective of the aDSM that may arise after the appointment.
3. Failure to attend three (3) consecutive Committee meeting without prior notification.