EAST AFRICAN COMMUNITY

HARMONIZED INDICATORS FOR ASSESSING AND MONITORING PHARMACOVIGILANCE SYSTEMS IN EAST AFRICAN COMMUNITY PARTNER STATES: USER MANUAL

JUNE 2016

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Acronyms and Abbreviations

ACT: Artemisinin-based combination therapy

ADE: Adverse drug event

ADR: Adverse drug reaction

AERS: Adverse Event Reporting System

AMFm: Affordable Medicines Facility malaria

AMRH: African Medicines Registration Harmonisation

ART: Antiretroviral therapy

ARV: Antiretroviral

BMGF: Bill & Melinda Gates Foundation

CPD: Continuous Professional Development

DTC: Drug and Therapeutic Committee

EAC: East African Community

EC: European Commission

FDA US Food and Drug Administration

GAVI: Global Alliance for Vaccines and Immunization

Global Fund: Global Fund to Fight AIDS, Tuberculosis and Malaria

GMP: Good Manufacturing Practices

ICH: International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use

IPAT: indicator-based pharmacovigilance assessment tool

ISO: International Standard Organization

IT: Information Technology

MAH: Marketing authorization holder

MOU: Memorandum of Understanding

MRH: Medicines Registration Harmonization

MSH: Management Sciences for Health

NDA: National Drug Authority [Uganda]

NMRA: National medicines regulatory authority

NPC: National Pharmacovigilance Center

PEPFAR: President's Emergency Plan for AIDS Relief

PHP: Public health program

PMI: President's Malaria Initiative

PPB: Pharmacy and Poisons Board, Kenya

PRAC: Pharmacovigilance Risk Assessment Committee

PSUR: Periodic safety update report

PV: Pharmacovigilance

RCORE: Regional centre of excellence

RF: Rockefeller Foundation

SOP: Standard operating procedure

SPS: Strengthening Pharmaceutical Systems Program

SRA: Stringent regulatory authority

SSA: Sub-Saharan Africa

TB: Tuberculosis

TFDA Tanzania Food and Drugs Authority

TOT: Training of Trainers

UMC: Uppsala Monitoring Centre [WHO]

USAID: US Agency for International Development

USD: US dollars

USP: United States Pharmacopeia

WHO: World Health Organization

Background

The East African Community (EAC) is a regional inter-governmental organization of the six Partner States namely: the Republic of Burundi, the Republic of Kenya, the Republic of Rwanda, the Republic of Southern Sudan, the United Republic of Tanzania and the Republic of Uganda, with its headquarters located in Arusha, Tanzania. The six (6) EAC countries cover an area of approximately 2.45 million square kilometres, a combined gross domestic product of about $ 160 billion and have an estimated population of over 157 million people who share a common history, language, culture and infrastructure. These advantages provide the Partner States with a unique framework for regional co-operation and integration in various political, economic, social and cultural areas of common interest including the harmonization of drug registration, without impeding or obstructing the movement of pharmaceuticals within the Community which is an explicit policy priority under Chapter 21 (Article 118) of the EAC treaty.

New initiatives have emerged, including the African Medicines Regulatory Harmonisation (AMRH) Initiative, aimed at ensuring rapid access to safe, efficacious, and good quality essential medicines by reducing the time to register medicines for the treatment of priority diseases. As part of regional cooperation on health, the EAC Partner States have initiated the process of harmonizing the regulation of the manufacture, import, trade, sale and export of all medicines and health supplies within the region through the legal mandate of the existing National Medicines Regulatory Authorities (NMRAs) in each of the Partner States. The initiation and institutionalisation of regional harmonization of medicines regulation will assist countries to fully realize the benefits of the growing pharmaceutical industry in the region and also to ensure easy access to affordable, safe and quality essential medicines and health supplies for both local use and export to the international markets.

Such harmonization initiatives strive to strengthen regulatory capacity and systems and better coordinate the registration process in Africa. However, these efforts aimed at strengthening medicines registration need to be matched by equally strong pharmacovigilance (PV) systems to ensure patient safety. Therefore, as many countries increase the number of products in their national medicines register, pharmacovigilance activities should equally be strengthened.

As more medical products become available and accessible in the market through improved registration, the safety, quality, and effectiveness of medical products should be continuously monitored and, therefore, AMRH and related initiatives need to incorporate PV into the process of strengthening regulatory capacity and systems.

Pharmacovigilance Systems in the East African Community Partner States

The EAC Partner States have basic structures for coordination of PV activities. However, the systems and structures differ from one partner state to the other. Pharmacovigilance guidelines, advisory committees, data collection tools/forms, designated staff, all exist in the Partner States' NMRAs. The functionality of Technical Advisory Committees varies from one Partner State to the other.

There are systems for reporting ADRs in all NMRAs; however, only five out of six NMRAs are reporting ADRs to the WHO Program for International Drug Monitoring. Currently Kenya is the only NMRA with an electronic pharmacovigilance reporting system.

Among the six NMRAs of the five Partner States, five NMRAs have safety policy and legal frameworks and 4 NMRAs (United Republic of Tanzania (mainland), Republic of Kenya, Republic of Rwanda and the Republic of Uganda) have safety regulations on pharmacovigilance for health professionals.

EAC Pharmacovigilance Harmonization Project

The EAC Pharmacovigilance Harmonization Project builds on previous gains under the Medicines Registration Harmonization Programme and sharing of best practices within the region with an initial outcome of reduced time of issuance of marketing authorization for medicines and hence improved service delivery in EAC Partner States NMRAs.

The goal of the EAC Pharmacovigilance Harmonization Project is promote patient safety through harmonisation and strengthening pharmacovigilance systems in the EAC partner states. The specific objectives of the project are:

- To develop and implement harmonized PV requirements, guidelines, procedures and practices for the regulation of medicines, health products and technologies in the EAC region.
- To build and strengthen institutional capacity on pharmacovigilance in the EAC Partner States.
- To support partnership and decision making through appropriate technology and information sharing on product safety.

Rationale and Objectives

When the EAC region embarked on the process of harmonizing their pharmacovigilance systems, the partner states did not have a common set of performance metrics for assessing pharmacovigilance systems within and across the countries that make up the EAC region. Performance metrics are required for standardized, consistent, and routine monitoring and evaluation of pharmacovigilance systems and medicine safety activities. Harmonized indicators and associated tools enable stakeholders to assess the status of their pharmacovigilance system and diagnose the system's strengths, weaknesses, and gaps; to design and plan interventions based on local situations, existing regulatory capacity and priorities, identified system gaps, and available resources; to monitor and evaluate pharmacovigilance and medicine safety activities; and to compare pharmacovigilance activities at country level and across regions. For the purposes of the EAC harmonization project, the harmonized indicators will be useful in establishing current capacity for safety monitoring and will allow longitudinal measurement of progress after interventions are implemented.

The goal of the harmonized indicators for assessing pharmacovigilance systems in EAC Partner States is to provide a common set of measures with which to assess, monitor, evaluate and compare pharmacovigilance systems in EAC partner states.

The specific objectives of the harmonized tools for assessing pharmacovigilance systems are:

1. To assess the status of the pharmacovigilance system in each of the EAC partner states.
2. To provide indicators for the monitoring and evaluation of pharmacovigilance activities, system capacity and performance.
3. To compare the status of pharmacovigilance systems across EAC partner states and establish trends, thereby helping to define the priorities for collaboration within the EAC.
4. To provide information for governments and other stakeholders to identify gaps and take appropriate, evidence-based action in ensuring drug safety.
5. To enable evaluation of the outputs, outcomes and impact of pharmacovigilance systems.

The use of these harmonized tools will guide the development of feasible interventions and recommendations to improve medicine and patient safety. The recommendations resulting from the analysis of the data generated will reflect each country's local realities, existing regulatory capacity and priorities, identified system gaps, and resources available for conducting medicine safety activities. Additionally, the standardized and indicator-based

approach included in the tools will allow longitudinal measurement of progress after the recommended interventions are implemented.

Scope

The harmonized indicators and assessment tools are suitable for evaluating the current state of pharmacovigilance systems through the collection, analysis, and interpretation of data on safety monitoring aspects of medicine regulation as defined by the EAC PV harmonization project under the EAC-MRH. Data are drawn from the NMRA/National PV Center), public health programs and a selection of health facilities in individual EAC partner states and can be compared and consolidated for the EAC region.

Development Process

The EAC Pharmacovigilance Indicators and Manual were developed through a consultative workshop of pharmacovigilance experts drawn from the EAC partner states, the EAC secretariat, USAID/SIAPS program, World Health Organization and World Bank. The consultative workshop was held in Nairobi, Kenya, November 9-13, 2015. This was followed by a teleconference of the Technical Working Group on Pharmacovigilance held on January 29, 2016. The final indicators and manual were approved at a workshop in Kigali, Rwanda, June 13-15, 2016.

The main reference documents, from which the indicators and tools were selected and adapted, were:

- *WHO Pharmacovigilance Indicators: A practical manual for the assessment of pharmacovigilance systems*[1]

- *Strengthening Pharmaceutical Systems (SPS) Program Indicator-Based Pharmacovigilance Assessment Tool: Manual for Conducting Assessments in Developing Countries*[2]

These reference documents are intended to serve as supplementary resources to this manual, particularly for detailed descriptions of the indicators. Where EAC indicators are the same or comparable to indicators in the WHO and IPAT tools, the corresponding indicator number/identifier has been listed (see indicator table below) to assist users in referencing additional information.

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[1] WHO: Pharmacovigilance Indicators: A Practical Manual for the Assessment of Pharmacovigilance Systems. World Health Organization: Geneva, 2015. http://www.who.int/medicines/areas/quality_safety/safety_efficacy/EMP_PV_Indicators_web_ready_v2.pdf

[2] Strengthening Pharmaceutical Systems (SPS) Program: Indicator-Based Pharmacovigilance Assessment Tool: Manual for Conducting Assessments in Developing Countries. Submitted to the USAID by the SPS Program. Arlington, VA: MSH, 2009. http://pdf.usaid.gov/pdf_docs/PNADS167.pdf

Classification of Indicators

The harmonized EAC Pharmacovigilance Indicators are comprised of:

- 46 indicators for NMRAs and national pharmacovigilance centres – 32 core and 14 supplementary
- 16 indicators for public health programs (PHP) – 8 core and 8 supplementary
- 7 indicators for health facilities (HF) – 2 core and 5 supplementary
- 5 supplementary indicators for marketing authorization holders (MAH)

Core indicators are considered essential, based on their measure of the minimum requirements for a functioning national pharmacovigilance system defined by WHO and EAC's specific objectives and activities under the PV harmonization program, thus factor into the overall score of the PV system being assessed. Supplementary indicators are related to more sophisticated aspects of a PV system and/or aspects that are of interest but not essential, and thus are not included in the score.

These indicators address five components of the pharmacovigilance and medicine safety system:

1. Policy, law, and regulation;
2. Systems, structures, and stakeholder coordination;
3. Signal generation and data management;
4. Risk assessment and evaluation; and
5. Risk management and communication.

The indicators are further classified by "structure," "process," or "outcome" according to the component of the system or type of result that they measure.

Intended Users of the indicators and tools

These indicators and tools are intended for use by national medicine regulatory authorities (specifically, the pharmacovigilance units or centres), public health programs, health facilities, and any other stakeholders in the EAC that are concerned with pharmacovigilance and medicine safety.

Data Collection

Methods

The primary methods of data collection for the EAC harmonized PV indicators are:

A. Document review - Many of the indicators require information from official documents either to answer the assessment questions or to validate the answers of respondents. A list of key documents related to PV that should be requested and reviewed to collect the necessary data for the indicators is included in Annex 2.

B. Key informant interviews – Interviews with individuals who are knowledgeable about the PV system and activities in their country are an important source of data for calculating the indicators as well as contextual information, which will enrich the interpretation and understanding of the results. For many of the indicators, responses from key informants to the assessment questions should be backed up and validated by review of related documents. When informants' responses cannot be verified by documentation, the assessment supervisor will be responsible for determining whether or not the informant's response alone is sufficient evidence.

Sources

The data will be collected from four sources within the health system:

A. Ministry of Health/National Medicines Regulatory Authority – The institution and unit at national level that is responsible for monitoring medicine safety and implementing pharmacovigilance activities for the country is the primary source of information and data for the indicators. The data will come from the responses of key NMRA and PV staff members to assessment questions, documents and other materials developed and used by the NMRA and PV Center, as well as any databases maintained at the national level.

B. Public health programs (PHP) – A sub-set of indicators are targeted specifically at specialized health programs, which have a significant role to play in monitoring the safety of the medicines they recommend and use for their target disease(s). PHPs to be considered for inclusion in the baseline assessment and on-going monitoring and evaluation of PV include: HIV/AIDS, malaria, tuberculosis, immunizations, and maternal and child health.

C. Health facilities (HF) – A selection of health facilities, which should be representative of the country in terms of facility type/level, geography and sector, are included in the assessment to provide information on the extent to which HFs are engaged in PV activities and contributing to the national system.

D. Marketing authorization holders (MAH) – A selection of marketing authorization holders are included in the assessment to provide information on the extent to which MAHs conduct PV activities to monitor the safety of their registered products and contribute to the national system.

The indicator data to be collected are either qualitative or quantitative. The data for the structural indicators are mainly qualitative, whereas those for process and outcome or impact indicators are quantitative.

Identification of samples

The sample selected for inclusion in the assessment should represent the NMRA/national pharmacovigilance centre, priority public health programs, health facilities and marketing authorization holders in the individual partner state.

- NMRA/national pharmacovigilance centre – The head of the NMRA or the national pharmacovigilance centre is an essential key informant for the NMRA indicators. Additional technical staff may be consulted for specific questions.
- Public health programs – Based on the health priorities of the EAC region, five national public health programs have been pre-selected for assessment in all partner states: HIV/AIDS, tuberculosis, malaria, immunizations and maternal and child health (MCH). The directors of the programs or technical staff responsible for treatment activities, including monitoring of medicine safety, should be among the key informants.
- Health facilities – A sample of 10-15 health facilities will be selected for assessment and monitoring. The sample should include representation of the following levels/types of facilities: health posts/dispensaries, health centres, district hospitals, regional hospitals and national/referral hospitals. In addition, the facilities should represent the public, private and faith-based sectors of the health system and the country's geography.
- Marketing authorization holders – A sample of 7-10 marketing authorization holders that represent manufacturers of generic and innovator pharmaceutical products for priority health conditions (e.g., HIV/AIDS, tuberculosis), including at least one local manufacturer, will be included in the assessment. Country representatives of the manufacturers/MAHs that do not operate in the country may serve as the key informants.

Frequency of administration of indicators

The frequency of administration of these indicators is either annually or once every three years. To obtain a baseline assessment, users may have to administer the entire set of indicators in the first year and in the subsequent year administer only the core annual indicators. After the baseline national

assessment, a unit of the health system that is involved in medicine safety can use relevant harmonized pharmacovigilance indicators for routine monitoring and evaluation of the unit's services as related to medicine safety in subsequent years.

Data management and analysis

A data analysis tool has been developed specifically for the EAC harmonized indicators. Each of the EAC partner states (and other stakeholders upon request) will enter the relevant data from their country into the tool, which will help them calculate indicators and generate a score for each of the five system components being assessed.

Interpretation of assessment findings

For a partner state to be regarded as having a minimally functional pharmacovigilance and medicine safety system, according to requirements defined by WHO and partners[3] (Annex 3), it must achieve all of the core indicators. The achievement of supplementary indicators can indicate the sophistication of development of the country's medicine safety system. When compiling indicators and interpreting results, EAC partner states should also consider background information on the health and pharmaceutical systems, as well as contextual information collected from documents and key informant interviews. The EAC Pharmacovigilance assessment tool is a continuous quality improvement tool, and users are encouraged to use it to benchmark progress over time.

[3] WHO: Minimum Requirements for a functioning Pharmacovigilance System. http://www.who.int/medicines/areas/quality_safety/safety_efficacy/PV_Minimum_Requirements_2010_2.pdf

EAC Harmonized Pharmacovigilance Indicators

NMRA or PV Unit

Indicator #	Core or Supplementary	Indicator Type	Indicator	Collection Frequency	Assessment Questions
Component 1. Policy, Law, and Regulation					
1.1	C	S	Existence of a policy document that contains essential statements on pharmacovigilance or safety of medicines, health products and technologies (stand alone or as a part of some other policy document)	3 years	Is there a national policy on pharmacovigilance or medicine safety, or a more general medicines policy that contains essential statements? When was the policy last reviewed? *Request documentation to verify.*
1.2	C	S	Existence of specific legal provisions for pharmacovigilance in the national medicines legislation or similar legislation	3 years	Are there legal provisions for pharmacovigilance or medicine safety in the medicines act or law? *Request documentation to verify.*
1.3	C	S	Legal provisions for Marketing Authorization Holders to monitor and report the safety and quality of their products	3 years	Is it mandatory by law or regulations for marketing authorization holders to conduct post marketing safety activities? *Request documentation to verify.* Is it mandatory by law or regulations for marketing authorization holder to report adverse drug reactions/medicine safety related issues? *Request documentation to verify.*
1.4	C	S	Existence of updated National Essential Medicines List that was reviewed with consideration of medicine safety	3 years	Is there an essential medicines list in use? Does the essential medicines list selection committee consult medicine safety

Indicator #	Core or Supplementary	Indicator Type	Indicator	Collection Frequency	Assessment Questions
			information		information?
					When was the list last reviewed? *Request documentation to verify.*
Component 2. Systems, Structures, and Stakeholder Coordination					
2.1	C	S	Existence of a national pharmacovigilance center with a clear mandate and structure	3 years	Is there a National pharmacovigilance center or any other body assigned the responsibility of monitoring safety of medicines?
					Is there a clear mandate and organizational structure for the pharmacovigilance center? *Request documentation to verify.*
					What is the organizational affiliation of the PV Center/Unit? (e.g. University, hospital pharmacy department, NMRA etc.)
2.2	C	S	The pharmacovigilance center has designated, qualified human resources to carry-out its functions	Annual	How many staff members (full-time equivalent) does the PV center have who are specifically responsible for carrying out its functions (technical and administrative)? *Request documentation to verify.*
					Do the technical staff in the pharmacovigilance center have professional or educational qualifications related to medicine, pharmacy/pharmaceutical, or related field (e.g. epidemiology, public health)?

Indicator #	Core or Supplementary	Indicator Type	Indicator	Collection Frequency	Assessment Questions
2.3	C	S	Existence of a dedicated financial provision or statutory budget for the pharmacovigilance center	Annual	Is there an annual budgetary allocation for pharmacovigilance activities or for the Pharmacovigilance Center?
					In the last fiscal year, how many funds were allocated by the MOH and donors for pharmacovigilance activities? *Please enter the amount in the Answer box and specify the currency in the Notes column. Request documentation to verify.*
2.4	C	S	Existence of a functional national medicine safety advisory committee	Annual	Does a national medicine safety advisory committee exist with the responsibility to provide technical advice on the safety of medicines to the regulatory authority?
					Has the national medicine safety advisory committee met at least twice in the previous 12 months? *Request documentation to verify.*
2.5	C	S	Existence of national pharmacovigilance guidelines developed or reviewed within the past 5 years	3 years	Does a national guideline for pharmacovigilance (or a related document) exist?
					Has the national pharmacovigilance guideline been developed or reviewed within the past 5 years?
					When were the guidelines last reviewed? *Request documentation to verify.*
2.6	C	S	Existence of standard operating procedures (SOPs) for conducting	Annual	Does the NMRA have SOPs for pharmacovigilance activities?

Indicator #	Core or Supplementary	Indicator Type	Indicator	Collection Frequency	Assessment Questions
			pharmacovigilance activities		When were the SOPs last reviewed? *Request documentation to verify.*
2.7	C	S	Existence of a mechanism to disseminate pharmacovigilance information (including one or more of the following: newsletters, information bulletin, website or phone line for dissemination of pharmacovigilance information)	Annual	Is there a mechanism in place to disseminate PV information?
					Is there a newsletter or information bulletin for dissemination of PV information? *Request documentation to verify.*
					Is there a website for dissemination of PV information?
					Is there a publicly advertised phone line to receive and provide medicine safety and PV information?
					Is there another mechanism for dissemination of PV information? *Please describe the mechanism in Notes*
2.8	C	S	Existence of harmonized pharmacovigilance curricula for key healthcare workers - **Pre-Service**	3 years	Is PV incorporated into the national **pre-service** curricula of **doctors?** *Request documentation to verify.*
					Is PV incorporated into the national **pre-service** curricula of **nurses?** *Request documentation to verify.*
					Is PV incorporated into the national **pre-service** curricula of **pharmacists?** *Request documentation to verify.*

Indicator #	Core or Supplementary	Indicator Type	Indicator	Collection Frequency	Assessment Questions
					Is the curriculum in use for **pre-service** training of healthcare workers the EAC harmonized PV curriculum? *Request documentation to verify.*
2.9	C	S	Existence of harmonized pharmacovigilance curricula for key healthcare workers - **In-Service**	3 years	Is there a pharmacovigilance training module, manual, or curriculum for **in-service** training of health care workers? *Request documentation to verify.* Is the curriculum in use for **in-service** training of healthcare workers the EAC harmonized PV curriculum? *Request documentation to verify.*
2.10	C	P	Number of healthcare workers trained in pharmacovigilance in the previous 12 months through in-service training program	Annual	How many healthcare workers has the center/program trained on PV in the previous 12 months (through **in-service** training)? *Request documentation to verify.* How many training events/sessions were conducted in the previous 12 months? *Request documentation to verify.*
2.11	C	S	Existence of a functioning platform, mechanism or strategy for the coordination of pharmacovigilance activities - **National Level**	Annual	Does a platform, mechanism or strategy for the coordination of pharmacovigilance activities (such as PV technical working group, forum or regularly scheduled meetings) exist among **national stakeholders**? Have the key **national stakeholders** been convened at least once in the previous 12 months? *Request documentation to verify.*

Indicator #	Core or Supplementary	Indicator Type	Indicator	Collection Frequency	Assessment Questions
2.12	C	S	Existence of a functioning platform, mechanism or strategy for the coordination of pharmacovigilance activities – **EAC Regional Level**	Annual	Does a platform, mechanism or strategy for the coordination of pharmacovigilance activities (such as PV technical working group, forum or regularly scheduled meetings) exist among **EAC stakeholders**?
					Have the key **EAC stakeholders** been convened at least once in the previous 12 months? *Request documentation to verify.*
					Has the NMRA/PV center participated in at least one EAC stakeholder meeting in the previous 12 months? *Request documentation to verify.*
2.13	S	S	Evidence of a linkage between the Medicines Safety Committee and EAC Pharmacovigilance risk assessment advisory committee (PRAAC)	3 years	Is there information exchange and sharing between the National Medicines and Therapeutics Committee with the EAC Pharmacovigilance Risk Assessment and Advisory Committee? *Request documentation to verify.*
2.14	S	S	Adoption and use of harmonized web-based pharmacovigilance training tools	3 years	Does the national pharmacovigilance center offer the EAC web-based pharmacovigilance training tools?
2.15	S	P	Evidence of consideration of safety data when developing and updating standard treatment guidelines	3 years	Are pharmacovigilance data considered when developing standard treatment guidelines? *Request documentation to verify.*
2.16	C	S	National pharmacovigilance center is a full or associate member of the WHO Program for International Drug Monitoring	Annual	Is the national pharmacovigilance center a full or associate member of the WHO Program for International Drug Monitoring?

Indicator #	Core or Supplementary	Indicator Type	Indicator	Collection Frequency	Assessment Questions
Component 3. Signal Generation and Data Management					
3.1	C	S	Existence of a national database for pharmacovigilance information	Annual	Does a central database exist for managing PV data? Does the central database contain data from various PV sources and methods? *Request documentation to verify.*
3.2	C	P	Evidence of a process or mechanism for sharing information with other regulatory functions, other regulatory agencies and global databases	Annual	Has information in the database been shared (either electronically or via report) with other regulatory functions, other regulatory agencies and/or global databases? *Request documentation to verify.*
3.3	C	S	Existence of a standard adverse event (AE) reporting form Subset indicators: The standard reporting form, or separate forms, provide for reporting of— - Adverse drug reactions - Suspected medication errors - Therapeutic ineffectiveness - Suspected misuse, abuse of and/or dependence on medicines	Annual	Is there a standard AE reporting form? *Request documentation to verify.* Are there relevant fields in the standard AE form (or a separate form) to report adverse drug reactions? Are there relevant fields in the standard AE form (or a separate form) to report suspected medication errors? Are there relevant fields in the standard AE form (or a separate form) to report therapeutic ineffectiveness?

Indicator #	Core or Supplementary	Indicator Type	Indicator	Collection Frequency	Assessment Questions
			- Adverse events following immunization (AEFI) - Medical devices and diagnostics		Are there relevant fields in the standard AE form (or a separate form) to report suspected misuse, abuse and/or dependence on medicines?
					Are there relevant fields in the standard AE form (or a separate form) to report AEFIs?
					Are there relevant fields in the standard AE form (or a separate form) to report adverse events related to medical devices and diagnostics?
3.4	C	S	Existence of a form (or section of ADE form) for reporting suspected product quality issues	Annual	Is there a form with relevant fields for reporting suspected/ observed poor quality issues? *Request documentation to verify.*
3.5	S	S	Existence of a form or mechanism for the public to report AEs (Patient reporting system)	Annual	Is there a standard reporting form for the general public to report AEs?
3.6	S	S	Existence of electronic AE reporting system that complies with international reporting format standards	3 years	Is there an electronic AE reporting system?
					Is the system compliant with the international reporting standards (E2B)?

Indicator #	Core or Supplementary	Indicator Type	Indicator	Collection Frequency	Assessment Questions
Component 4. Risk Assessment and Evaluation					
4.1	C	P	Total number of AE reports received in the previous 12 months (also expressed as number of AEs per 100 000 persons in the population) Sub-indicators: - ADR - Suspected medication errors - Therapeutic ineffectiveness - Suspected misuse, abuse, dependence - AEFI - AE related to medical devices and diagnostics	Annual	What is the total number of AE reports received in the previous 12 months? *Request documentation to verify.* Of the total, what is the number of reports of ADR? Of the total, what is the number of reports of suspected medication errors? Of the total, what is the number of reports of therapeutic ineffectiveness? Of the total, what is the number of reports of suspected misuse, abuse, dependence? Of the total, what is the number of reports of AEFI? Of the total, what is the number of reports of AE related to medical devices and diagnostics? What is the total population of the country?
4.2	C	P	Number and percentage of total AE reports received by the national pharmacovigilance center in the previous 12 months from: - Marketing Authorization Holders - PHPs - Health care providers - Patients	Annual	What is the number of AE reports received by the national pharmacovigilance center in the previous 12 months from marketing authorization holders? What is the number of AE reports received by the national pharmacovigilance center in the previous 12 months from public health programs?

Indicator #	Core or Supplementary	Indicator Type	Indicator	Collection Frequency	Assessment Questions
					What is the number of AE reports received by the national pharmacovigilance center in the previous 12 months from healthcare providers?
					What is the number of AE reports received by the national pharmacovigilance center in the previous 12 months from patients?
					What is the total number of AE reports received in the previous 12 months?
4.3	C	P	Number and percentage of total AE reports received that are entered in the national database in the previous 12 months	Annual	What is the total number of ADE reports received that have been entered in the national database in the previous 12 months?
					What is the total number of ADE reports received in the previous 12 months?
4.4	C	P	Number and percentage of safety reports received at national level that have been submitted to the EAC regional database in the previous 12 months	Annual	What is the total number of AE reports that have been entered in the EAC database in the previous 12 months? *Request documentation to verify.*
					What is the total number of AE reports received in the previous 12 months?
4.5	C	P	Number and percentage of total AE reports acknowledged and/or issued feedback in the previous 12 months	Annual	What is the total number of AE reports acknowledged/issued feedback in the previous 12 months?
					What is the total number of AE reports received in the previous 12 months?

Indicator #	Core or Supplementary	Indicator Type	Indicator	Collection Frequency	Assessment Questions
4.6	C	P	Number and percentage of ADE reports subjected to causality assessment in the previous 12 months	Annual	What is the total number of AE reports subjected to causality assessment in the previous 12 months? What is the total number of ADE reports received in the previous 12 months?
4.7	C	P	Number and percentage of ADE reports committed to VigiBase in the previous 12 months	Annual	How many of the ADE reports received at the national pharmacovigilance center were committed to Vigibase in the previous 12 months? What is the total number of ADE reports received in the previous 12 months?
4.8	C	P	Average completeness score of quarterly reports committed to VigiBase in the previous four quarters (= one year)	Annual	What was the average completeness score of quarterly reports committed to Vigibase in the previous four quarters? *Consult quarterly reports from VigiGrade for completeness scores of submitted reports*
4.9	C	P	Number of active surveillance activities initiated, ongoing or completed during the previous three years	3 years	How many active surveillance studies have been conducted in the last three years (36 months)? Indicate what type (e.g. cohort event monitoring, targeted spontaneous reporting, etc.) and stage of completion (e.g. initiated, on-going or completed) for each study. *Request documentation to verify.*
4.10	S	P	Number and percentage of total AE reports received at the national pharmacovigilance center in the previous	Annual	What is the number of AE reports received in the previous 12 months submitted by **doctors**?

Indicator #	Core or Supplementary	Indicator Type	Indicator	Collection Frequency	Assessment Questions
			12 months from healthcare providers by type of provider		What is the number of AE reports received in the previous 12 months submitted by **nurses**?
					What is the number of AE reports received in the previous 12 months submitted by **pharmacists**?
					What is the total number of AE reports received in the previous 12 months?
4.11	S	P	Evidence of supervision visits to marketing authorization holders by NMRA that address PV	Annual	Does the NMRA conduct supervision visits of MAHs that address PV?
					How many supervision visits have been conducted in the previous 12 months?
Component 5. Risk Management and Communication					

Indicator #	Core or Supplementary	Indicator Type	Indicator	Collection Frequency	Assessment Questions
5.1	C	O	Number of regulatory actions taken in the previous 12 months as a consequence of national pharmacovigilance activities including: - Number of product label changes (variation); - Number of safety warnings on medicines to health professionals and general public; - Number of withdrawals of medicines; - Number of other restrictions on use of medicines; - Number of treatment guideline/policy changes *Request documentation to verify.*	Annual	How many regulatory actions were taken in the preceding 12 months as a consequence of pharmacovigilance activities that resulted in ***product label changes (variation)***?
					How many regulatory actions were taken in the preceding 12 months as a consequence of pharmacovigilance activities that resulted in ***safety warnings on medicines to health professionals***?
					How many regulatory actions were taken in the preceding 12 months as a consequence of pharmacovigilance activities that resulted in ***safety warnings on medicines to the general public***?
					How many regulatory actions were taken in the preceding 12 months as a consequence of pharmacovigilance activities that resulted in ***withdrawals of medicines***?
					How many regulatory actions were taken in the preceding 12 months as a consequence of pharmacovigilance activities that resulted in ***treatment guideline/policy changes***?
					How many regulatory actions were taken in the preceding 12 months as a consequence of pharmacovigilance activities that resulted in ***other restrictions on use of medicines***?

Indicator #	Core or Supplementary	Indicator Type	Indicator	Collection Frequency	Assessment Questions
5.2	C	O	Number of signals detected in the past 3 years by the pharmacovigilance center	3 years	How many signals were detected in the past 3 years by the pharmacovigilance center?
5.3	S	O	Average time lag between identification of safety signal of a serious ADR or significant medicine safety issue generated nationally and communication to health care workers and the public	Annual	How long does it take from when a safety signal or significant safety issue is identified to when it is communicated to health workers and the public? *Please answer in days.*
5.4	S	O	Number of suspected product quality issues detected through the pharmacovigilance system	Annual	What is the number of suspected product quality issues detected through the pharmacovigilance system in the previous 12 months? *Request documentation to verify.*
5.5	S	O	Percentage of planned issues of the medicine safety bulletin (or any other health-related newsletter that routinely features ADR or medicine safety issues) published in the previous 12 months	Annual	How many issues of the medicine safety bulletin are supposed to be published per year? How many issues of the medicine safety bulletin were published in the previous 12 months? *Request documentation to verify.*
5.6	S	O	Number of products voluntarily withdrawn by marketing authorization holders because of safety concerns in the previous 12 months	Annual	How many products were voluntarily withdrawn by marketing authorization holders because of safety concerns in the previous 12 months?
5.7	S	O	Number and percentage of medicine safety information requests addressed in the previous 12 months	Annual	How many requests for information about medicine safety were received in the previous 12 months? *Request documentation to verify.* Of the total received, how many requests for medicine safety information were addressed in the previous 12 months?

Indicator #	Core or Supplementary	Indicator Type	Indicator	Collection Frequency	Assessment Questions
5.8	S	O	Number of medicine safety issues of local relevance identified from outside sources (e.g., from another country, from EAC region or international sources) and acted on locally in the previous 12 months	Annual	How many medicine safety issues identified from outside sources were acted on locally in the previous 12 months? *Request documentation to verify.*
5.9	S	O	Number of public or community education activities relating to medicine safety carried out in the previous 12 months	Annual	How many public or community education activities relating to medicine safety were carried out in the previous 12 months? *Request documentation to verify.*

Indicator #	Core or Supplementary	Indicator Type	Indicator	Collection Frequency	Assessment Questions
Component 1. Policy, Law, and Regulation					
Component 2. Systems, Structures, and Stakeholder Coordination					
P2.1	C	P	Pharmacovigilance activities included within the strategic and/or annual operational plans of public health programs	Annual	Are pharmacovigilance activities included within the strategic and/or annual operational plans of public health programs? *Request documentation to verify.*
P2.2	C	S	Existence of a dedicated financial provision or statutory budget for the PHPs	Annual	Is there an annual budgetary allocation for pharmacovigilance activities for the PHP? *Request documentation to verify.* In the last fiscal year, how many funds were allocated by the MOH and donors for pharmacovigilance activities? *Please enter the amount in the Answer box and specify the currency in the Notes column.*

Indicator #	Core or Supplementary	Indicator Type	Indicator	Collection Frequency	Assessment Questions
P2.3	C	S	Existence of a mechanism to disseminate pharmacovigilance information (including one or more of the following: newsletters, information bulletin, website or phone line for dissemination of pharmacovigilance information)	Annual	Is there a mechanism in place to disseminate PV information?
					Is there a newsletter or information bulletin for dissemination of PV information? *Request documentation to verify.*
					Is there a website for dissemination of PV information?
					Is there a publicly advertised phone line to receive and provide medicine safety and PV information?
					Is there another mechanism for dissemination of PV information? *Please describe the mechanism*
P2.4	C	P	Number of healthcare workers trained in pharmacovigilance in the previous 12 months through in-service training	Annual	How many healthcare workers has the center/program trained on PV in the previous 12 months (through **in-service** training)? *Request documentation to verify.*
					How many training events/sessions were conducted in the previous 12 months? *Request documentation to verify.*
P2.5	C	P	Number of national treatment guidelines or protocols in use within the public health programs that consider pharmacovigilance	Annual	Do the treatment guidelines or protocols in use in the PHP provide instruction for PV activities? *Request documentation to verify.*

Indicator #	Core or Supplementary	Indicator Type	Indicator	Collection Frequency	Assessment Questions
P2.6	S	P	Evidence of consideration of safety data when developing and updating standard treatment guidelines or treatment policies	3 years	Are pharmacovigilance data considered when developing standard treatment guidelines? *Request documentation to verify.*
Component 3. Signal Generation and Data Management					
P3.1	C	P	PHPs use the national, standard ADR/AE reporting form	Annual	Does the PHP use the national, standard ADR/AE reporting form?
Component 4. Risk Assessment and Evaluation					
P4.1	C	P	Number and percentage of ADR/AE reports received by PHPs that were submitted to the national pharmacovigilance center in the previous 12 months	Annual	What is the number of AE reports received by the PHP in the previous 12 months? What is the number of AE reports submitted by the PHP to the national PV center in the previous year?
P4.2	C	P	Number of active surveillance activities initiated, ongoing or completed during the past three years	3 years	How many active surveillance studies have been conducted in the last three years (36 months)? Indicate what type (e.g. cohort event monitoring, targeted spontaneous reporting, etc.) and stage of completion (e.g. initiated, on-going or completed) for each study Request *documentation to verify*
P4.3	S	O	Percentage of patients in public health programs for whom drug-related, serious unexpected adverse events were reported	Annual	What is the total number of patients receiving medicines under the PHP? *Request documentation to verify.*

Indicator #	Core or Supplementary	Indicator Type	Indicator	Collection Frequency	Assessment Questions
			in the previous 12 months		What is the total number of patients receiving medicines in the PHP who experienced drug-related, serious, unexpected adverse events? *Request documentation to verify.* How many of those were reported to the national PV center? *Request documentation to verify.*
Component 5. Risk Management and Communication					
P5.1	S	O	Average time lag between identification of safety signal of a serious ADR or significant medicine safety issue generated nationally and communication to health care workers and the public	Annual	How long does it take from when a safety signal or significant safety issue is identified to when it is communicated to health workers and the public? *Please enter your answer in days.*
P5.2	S	O	Number of suspected product quality issues detected through public health programs	Annual	What is the number of suspected product quality issues detected through the PHP in the previous 12 months?
P5.3	S	O	Existence of a program-related newsletter that routinely features ADR or medicine safety information	Annual	Is there a program-related newsletter, bulletin or other publication that routinely features ADR or medicine safety information?
P5.4	S	O	Number and percentage of medicine safety information requests addressed in the previous 12 months	Annual	How many requests for information about medicine safety were received in the previous 12 months? *Request documentation to verify.*

Indicator #	Core or Supplementary	Indicator Type	Indicator	Collection Frequency	Assessment Questions
					How many requests for medicine safety information were addressed in the previous 12 months? *Request documentation to verify.*
P5.5	S	O	Number of medicine safety issues of local relevance identified from outside sources (e.g., from another country, from EAC region or international sources) and acted on locally in the previous 12 months	Annual	How many medicine safety issues identified from outside sources were acted on locally in the previous 12 months? *Request documentation to verify.*
P5.6	S	O	Number of public or community education activities relating to medicine safety carried out in the previous 12 months	Annual	How many public or community education activities relating to medicine safety were carried out by the PHP in the previous 12 months? *Request documentation to verify.*

Indicator #	Core or Supplementary	Indicator Type	Indicator	Collection Frequency	Assessment Questions
Component 1. Policy, Law, and Regulation					
Component 2. Systems, Structures, and Stakeholder Coordination					
F2. 1	C	S	Existence of a mechanism to disseminate pharmacovigilance information (including one or more of the following: newsletters, information bulletin, website or phone line for dissemination of pharmacovigilance information)	Annual	Is there a mechanism in place to disseminate PV information in your health facility?
					Is there a newsletter or information bulletin for dissemination of PV information? *Request documentation to verify.*
					Is there a website for dissemination of PV information?
					Is there a publicly advertised phone line to receive and provide medicine safety and PV information?
					Is there another mechanism for dissemination of PV information? *Please describe the mechanism in Notes*
F2. 2	C	P	Number of healthcare workers trained in pharmacovigilance in the previous 12 months through **in-service** training	Annual	How many healthcare workers has the facility trained on PV in the previous 12 months (through **in-service** training)? *Request documentation to verify.*
					How many training events/sessions were conducted in the previous 12 months? *Request documentation to verify.*

Indicator #	Core or Supplementary	Indicator Type	Indicator	Collection Frequency	Assessment Questions
Component 3. Signal Generation and Data Management					
F3.1	S	P	Percentage of surveyed healthcare facilities with functional pharmacovigilance (submitted >10 ADE reports to the national pharmacovigilance center in the previous 12 months) (Facility level: Healthcare facility submitted >10 AE reports to the national pharmacovigilance center in the previous 12 months)	Annual	How many AE reports did the health facility submit to the national pharmacovigilance center in the previous 12 months?
Component 4. Risk Assessment and Evaluation					
Component 5. Risk Management and Communication					
F5.1	S	O	Percentage of surveyed health facilities that has Drug and Therapeutics Committees that have carried out pharmacovigilance activities or addressed medicine safety issues in the previous 12 months	Annual	Does the health facility have a Drug and Therapeutics Committee? Within the previous 12 months, has the DTC carried out any pharmacovigilance activities or addressed medicine safety issues? *Request documentation to verify.*
F5.2	S	O	Number of suspected product quality issues detected through surveyed health facilities	Annual	What is the number of suspected product quality issues detected at the health facility e in the previous 12 months?
F5.3	S	O	Number and percentage of medicine safety information requests addressed in the previous 12 months	Annual	How many requests for information about medicine safety were received in the previous 12 months? *Request documentation to verify.*

Indicator #	Core or Supplementary	Indicator Type	Indicator	Collection Frequency	Assessment Questions
					How many requests for medicine safety information were addressed in the previous 12 months? *Request documentation to verify.*
F5.4	S	O	Number of public or community education activities relating to medicine safety carried out in the previous 12 months	Annual	How many public or community education activities relating to medicine safety were carried out by the health facility in the previous 12 months?

Marketing Authorization Holders

Indicator #	Core or Supplementary	Indicator Type	Indicator	Collection Frequency	Assessment Questions
Component 1. Policy, Law, and Regulation					
Component 2. Systems, Structures, and Stakeholder Coordination					
M2.1	S	S	Percentage of surveyed marketing authorization holders that has a designated qualified (QPV) pharmacovigilance person (MAH: Existence of a qualified pharmacovigilance person at the MAH)	Annual	Is there a designated qualified pharmacovigilance person (QPV) at the company? *Request documentation to verify.*
Component 3. Signal Generation and Data Management					
Component 4. Risk Assessment and Evaluation					
M4.1	S	S	Percentage of surveyed marketing authorization holders that have procedures for the collection and reporting of safety issues (e.g. ICSRs and PSURs) to the NMRA	Annual	Does the marketing authorization holder have procedures in place for collecting and reporting safety issues to the NMRA? *Request documentation to verify*
Component 5. Risk Management and Communication					
M5.1	S	O	Number and percentage of risk mitigation plans currently in place that are targeted at high-risk medicines that have been submitted to the NMRA	Annual	Does the MAH have any risk mitigation plans currently in place for high-risk medicines? How many risk mitigation plans are in place? How many risk mitigation plans have been submitted to the NMRA?

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Annex 2.

List of Supporting Documents
National policy on pharmacovigilance or national medicines policy
National medicines act or legislation
Regulatory systems, governance, and policy
National policy on PV or medicine safety (where it exists)
National guideline or standard operating procedure for Pharmacovigilance
National guideline or standard operating procedure for Quality Assurance
National guideline or standard operating procedure for Public Health Programs (workers' manual, treatment guideline, treatment policy documents as they relate to adverse events and patient safety etc.)
Organization chart/details of pharmacovigilance center or unit
Organization chart of drug safety advisory committee (where it exists)
Annual (or periodic) PV center or program report and activity reports
Medicines safety bulletins
Medicine safety newsletter
Medicine safety alerts
Ministry of Health circular
Meeting minutes of national medicines safety advisory committee and DTCs
PV information management tools, including:
ADR database
Annual report or activity report (PHP)
Annual report or activity report (PV unit)
Report on active surveillance activities, if any
Survey report on quality of pharmaceutical products, if any
Study report to detect medication errors, if any
Report on medicine use studies, if any
Form for reporting adverse drug reactions (ADRs)
Form for reporting product quality problems
Form for reporting medication errors
Form for reporting treatment failures
Form for reporting by patients
Reports on pharmaceutical market size and industry drug safety activities
Risk mitigation plans (+risk mitigation plan submitted by industry)
Safety alerts from outside sources
Safety issues identified locally
Performance reports on DTCs

Annex 3.

Minimum Requirements for a functional Pharmacovigilance System

Functions of a National Pharmacovigilance System

The functions of a national pharmacovigilance system include the following:

1. To promote PV in the country, notably, to collect and manage adverse drug reaction (ADR) reports, reports of medication errors and suspected counterfeit/substandard drugs; to collaborate and harmonize with existing ADR collection activities within the country (e.g., national disease control programmes, Ministry of Health etc.) as well as international cohorts monitoring ADRs in defined patients or populations.

2. To identify signals of medicine safety i.e., unknown or poorly characterized adverse events in relation to a medicine or a combination of medicines and/or its use.

3. To undertake assessment of risk and options for risk management.

4. To identify if there are quality problems in medicines resulting in ADRs; and more generally, support the identification of medicine quality issues.

5. To provide effective communication on aspects related to medicine safety, including dispelling unfounded rumors of toxicity attributed to medicines and/or vaccines.

6. To apply resulting information from pharmacovigilance for the benefit of public health
programmes, individual patients and national medicines policies and treatment guidelines.

7. To develop and maintain drug utilization information.

8. To identify issues associated with unregulated prescribing and dispensing of medicines.

Minimum Requirements for a Functional National Pharmacovigilance System

The following are the **minimum** requirements that the WHO and partners agree should be present in any national pharmacovigilance system.

1. A national pharmacovigilance centre with designated staff (at least one full time), stable basic funding, clear mandates, well defined structures and roles and collaborating with the WHO Programme for International Drug Monitoring.

2. The existence of a national spontaneous reporting system with a national individual case safety report (ICSR) form i.e. an ADR reporting form.

3. A national database or system for collating and managing ADR reports.

4. A national ADR or pharmacovigilance advisory committee able to provide technical assistance on causality assessment, risk assessment, risk management, case investigation and, where necessary, crisis management including crisis communication.

5. A clear communication strategy for routine communication and crises communication.

(see PowerPoint presentation: 'Minimum requirements for pharmacovigilance in countries', http://www.who.int/medicines/areas/quality_safety/safety_efficacy/PV_Minimum_Requirements_presentation.ppt).