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SECURE WEBINAR 19

Enhancing the Quality and Safety of Medicine in Southeast Asia

11 December 2024

Mrs. Soulyvanh Keokinnaly
Chief of Hospital Pharmacy Management Division
Food and Drug Department, Ministry of Health Lao PDR

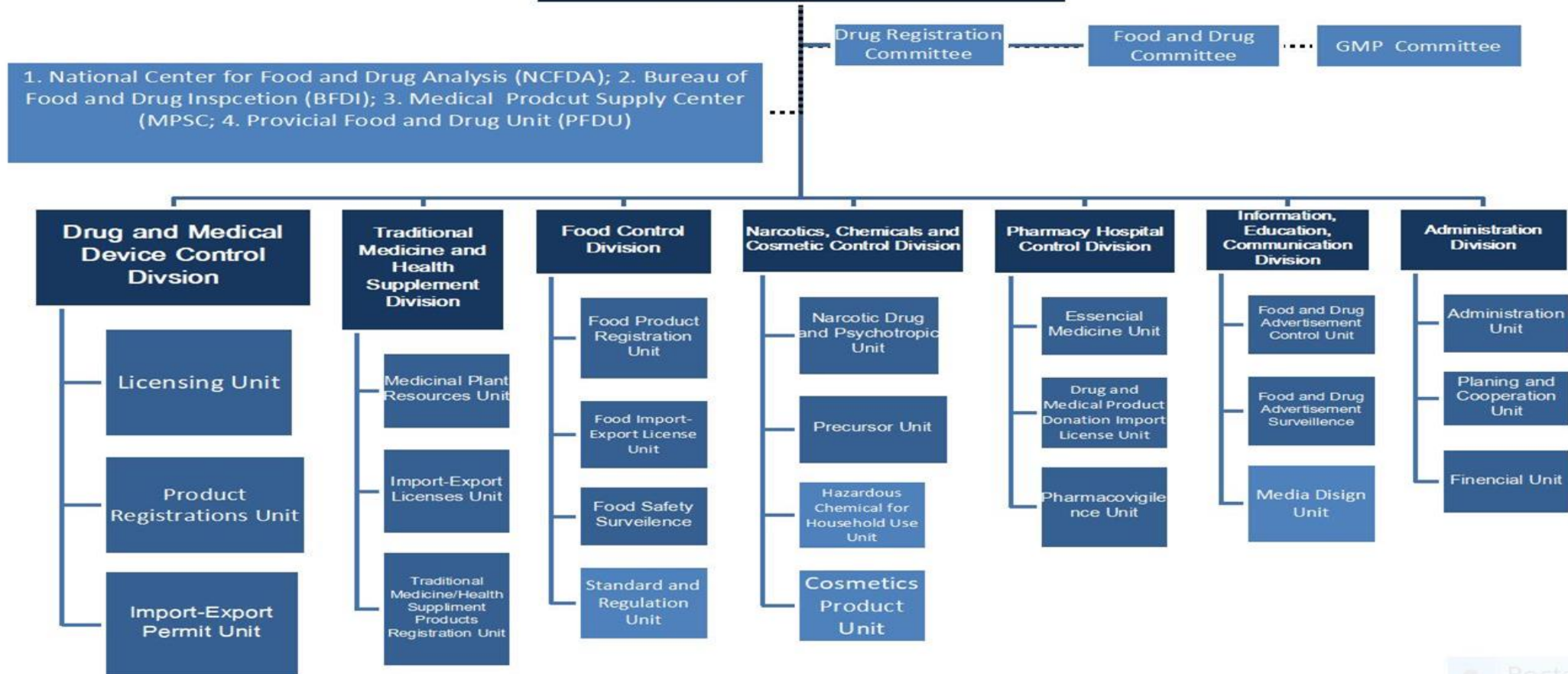
Content of presentation

- Organization chart
- Legislations
- PV System
- Challenges
- Next Step



Organization chart

Food and Drug Department Organization Chart



Legislations

- National Medicine Policy (1st Revision, 2003)
- Law on Drug and Medical Products No: 07/NA , date: 21 December 2011
- Law on consumer protection (Articles 10, 11; 22; 24; 32;58 No. 02/NA; 30 June, 2010)
- National Guideline for Pharmacovigilance
- Law on Immunization No: 52/NA, dated 25/06/2018
- AEFI Guideline 2022
- AEFI Committee No 3924/MoH, dated 23/12/2021
- Hospital Pharmacy Development Plan 2021-2030

VIGILANCE (VL)

- Lao PDR be member WHO UMC in 2015
- AEFI and ADR reporting system (VigiFlow and DHIS2 established), shared with relevant national institutions, and causality assessment committee meets regularly and review serious AEFI/ADR cases

VigiFlow - Food and Drug Department, Ministry of Health

Soulyvanh Keokinnaly

+ New ICSR + New AEFI Import VigiLyze

Filter PDF/Excel/XML

0 reports selected 1138 reports match your search with 1 filters applied Page 1 of 57

	Worldwide unique id	Initials	Date of birth	Reaction / event (MedDRA)	Drug name (WHODrug)	Initial received date	Latest received date	Status of report	VigiLyze
<input type="checkbox"/>	LA-FDD-300021714	CH_STL_2024_0001	1995	Skin rash, Difficulty breathing, Fever	Sonke tenofovir, 3tc, Dolutegravir, Bactrim forte	22102024	22102024	Open	✓
<input type="checkbox"/>	LA-FDD-300021712	CPS_2024_0001	1986	Skin rash, Non-cardiac chest pain, Difficulty breathing	Ceftriaxon	22102024	22102024	Open	✓
<input type="checkbox"/>	LA-FDD-300021713	BKO_2024_0002	19102016	Itchy rash	Metamizol	22102024	22102024	Open	✓
<input type="checkbox"/>	LA-FDD-300021711	MCH_2024_0021	11062024	Diarrhoea, Vomiting, Breast feeding problem (infant)	Vacuna Pentavalente (DPT+ HB+ Hib) Adsorbida	21102024	21102024	Open	✓
<input type="checkbox"/>	LA-FDD-300021710	MCH_2024_0020	11062024	Diarrhoea, Vomiting, Breast feeding problem (infant)	Vacuna Pentavalente (DPT+ HB+ Hib) Adsorbida	21102024	21102024	Open	✓
<input type="checkbox"/>	LA-FDD-300021708	MCH_2024_0019	21042024	Fever, Vomiting	Bcg vaccine	09082024	09082024	Open	✓
<input type="checkbox"/>	LA-FDD-300021707	MCH_2024_0018	02072022	Fever, Diarrhoea, Vomiting	Measles, Rubella	09082024	09082024	Open	✓

Gavi World Health Organization Lao PDR

ວິທີການປ້ອນຂໍ້ມູນ ຫາປາວຊຸ ເຂົ້າໃນລະບົບ DHIS2

ວິທີການປ້ອນຂໍ້ມູນ ຫາປາວຊຸ ເຂົ້າໃນລະບົບ DHIS2 | how to enter AEFI data into DHIS2

EPI Lao PDR 717 subscribers

5 Share Download Clip Save

Tools

ແບບຟອມລາຍງານ ກໍລະນີ ຫາຍາດ (AEFI Reporting Form)

ຂໍ້ມູນທົ່ວໄປຂອງກໍລະນີ

*ຊື່ ແລະ ນາມສະກຸນ: _____ ຊື່ ແລະ ນາມສະກຸນຜູ້ລາຍງານ _____

*ອາຍຸ: _____ ປະເພດ: _____ ນັກສູນ: _____

*ຖິ່ນ: ເດືອນ/ເລກທີ/ຫ່ວຍ _____ ບ້ານ _____ ເມືອງ _____ ແຂວງ _____

ເປັນໂຕຕິດ: _____

*ເພດ: ຊາຍ ບິງ (ຖືພາ ກຳລັງໃຫ້ນົມລູກ), ອາຊີບ _____

*ວັນເກີດ (ວັນເດືອນປີ): ____/____/____

ຫຼື ອາຍຸໃນມື້ເລີ່ມວັກຊີນ: ____ ວັນ _____ ວັນ _____

ຫຼື ກຸ່ມອາຍຸ: < 1 ປີ; 1 ຫາ 5 ປີ; > 5 ປີ - 18 ປີ; > 18 ປີ - 45 ປີ; > 45 ປີ - 60 ປີ; > 60 ປີ

*ວັນທີ່ໃຫ້ແກ້ໄຂໄດ້ ຈຶ່ງກ່ຽວກັບກໍລະນີ: ____/____/____

*ວັນທີ່ລາຍງານ: ____/____/____

*ຊື່ ສະຖານທີ່ບໍລິການສຸຂະພາບ ຫຼື ຈຸດ ທີ່ໃຫ້ບໍລິການວັກຊີນ: _____

ວັກຊີນ (ລາຍງານຫາວັກຊີນທີ່ກໍລະນີ ນີ້ ໄດ້ຮັບໃນ 30 ວັນກ່ອນ)

ຊື່ວັກຊີນ ແລະ ບໍລິສັດ ຜູ້ຜະລິດ	*ຊື່ວັກຊີນ	*ວັນທີ່ໃຫ້ວັກ ຊີນ	*ເວລາໃຫ້ ວັກຊີນ	*ເລກບັນຍາຍ ວັກຊີນ	*ວັນທີ່ໃຫ້ ອາຍຸ	ເລີ່ມຕາງ ການໃຫ້ວັກ ຊີນ

ນ້ຳໜັກ _____ ຄວາມສູງ _____

ຊື່ນ້ຳໜັກປະສົມ	ເລກບັນຍາຍ	ວັນທີ່ປະສົມ	ເວລາປະສົມ	ວັນທີ່ໃຫ້ ອາຍຸ

*ຕາມການປະຕິບັດ
ໃຫ້ແນ່ນອນ (*) ໃຊ້ໂທກຸ່ມອາຍຸຂອງກໍລະນີທີ່ກຳນົດຕົວເອງ:

ປະຕິບັດບໍລິເວນສັກຖືກແຈ້ງ (ເຊັ່ນ ໄດ້, ບວມ, ແດງ);
(O ມີອາການແຕ່ຍາກວ່າ ອ ມີ O ມີອາການບວມແຕ່ລວມໄປກຳລັງ
ຮັບວັກຊີນບໍລິເວນສັກຖືກວັກຊີນທີ່ອຸດ (ເຊັ່ນ ລວມກະຊວງສຸຂະພາບ)

ວິນິດັດເປັນກອງ ບໍລິເວນສັກ
 ລາກກະຊວງ ໄດ້ (O ໃຫຍ່ > 1.5 cm O ມີໂຕກອນນ້ຳຮຸ່ນ)

ໄດ້ເຮັດສູນ > 38 °C ລຳບວກກວມ 3 ວັນ

ອາການແພ້ອນແຂງ (Anaphylaxis)

ມີອາການຊັກ (O ຊືກແນ່ນອນມີໄຂ້ O ຊືກແນ່ນອນບໍ່ມີໄຂ້)

ກາບເຂັ້ມ

ເມັດ

ວິນິດັດ

ເຈັບຫົວ

ບໍ່ລວມ

ຖອກອອກ

ຈັບຫ້ອງ

ເປັນນິເກນເປີດຕັ້ງ

ການເຮັດບໍ່ແນ່ນອນ (ສຳລັບເດັກ)

ແຂນອ່ອນແຂງ

ເຈັບຫົວອັກ

ຫາບໃຈຫາກ

ໄຂ້ຂະໜອງອັກແຂນ

ຍ້ອງໄຫ້ບໍ່ຜຸດ (Persistent crying)

ອັນນະພາບກ້າມເສັ້ນອ່ອນແຫຼວ (Paralysis)

ອາການເສັ້ນເມືອ (Toxic shock syndrome)

ພາວະເມັດເລືອດບໍ່ເຂັ້ມ (Thrombocytopenia)

ອື່ນໆ (ໃຫ້ລະຫຼັງ)

ຂໍ້ແລະນາມສະກຸນ _____ ຊື່ ແລະ ນາມສະກຸນຜູ້ລາຍງານ _____

*ຮູບສະໜັບສະໜູນ

ຊື່ ແລະ ນາມສະກຸນ: _____ ວັນເດືອນປີ: ____/____/____

ຕີໂຮງໝໍ: _____ ທີ່ໂຮງໝໍ: _____

ເບີໂທ: _____ ອີເມວ: _____ ເລກທີ: _____

ລາຍເຊັນ: _____ ຍິ່ງມີບັນຫາສະໜັບສະໜູນ: _____

AEFI Job aid for frontline health workers
What would you do after you identify an AEFI?

What is an Adverse Event after Immunization (AEFI)?
An AEFI is any negative medical occurrence that follows immunization, expected or not, vaccine related or not.

What should I do after I detect an AEFI?
Provide treatment or transfer to higher-level treatment if needed. Communicate with the vaccine recipient/caregiver/family. Collect information on the vaccine and the symptoms, and fill in the form.

Is the case meeting any of the condition below?
Is it a serious AEFI?
• death case, life-threatening,
• Hospitalized case
• results in persistent or significant disability/incapacity,
• congenital anomaly, birth defect
• requires intervention to prevent permanent impairment or damage.
Is the case creating parent, family or community concern?

Yes
URGENT phone call to DHO/PHD
Send the AEFI REPORT FORM within 24 hours from detection via WhatsApp to DHO/PHD *

Yes
Send the AEFI REPORT FORM within 7-10 days from detection via WhatsApp to DHO/PHD *

Yes
Seek support from DHO/PHD for communication and case management.

Send AEFI report of AGGREGATE DATA to DHO/PHD
Monthly for routine immunization and daily for COVID-19 vaccines

Yes
2 or more place
Yes
Could be
e.g. local or muscular
Unusual
e.g. Fever or local than 3 days

*** How to send the report?**
HF Fill in the AEFI reporting form take a picture of the form and send them to DHO - PHD via NIP/MCHC via WhatsApp.

You can prevent AEFIs by providing the best practice everyday

Before vaccination

- Inform the parents/vaccine recipient about the importance and benefit of vaccine and possible minor reactions (fever, local pain, redness, swelling). These symptoms will resolve by 1 - 2 days
- Check the vaccine recipient
 - Body temperature (<38 C)
 - Breathing (for infant)
 - Inquire about medical history (for infants, inquire the mother about pregnancy and child delivery)
- Previous allergic reaction to vaccines

Check the vaccine

- Ensure it is the correct vaccine according to the immunization schedule
- Expiry date
- Vaccine Vial Monitor (VVM) and check the liquid

During vaccination

- Calm the vaccine recipient and caregiver
- For infants, advise the caregiver to hold the child in a comfortable position, and for adults, advise the vaccine recipient to sit comfortably
- Use correct immunization technique (drop ensure)

After vaccination

- Ask vaccine recipient/caregiver to stay at the health facility for observation for 15 - 30 mins
- Instruct the vaccine recipient/caregiver on what to do when minor reaction take place, such as fever, local pain, redness, swelling
- Instruct the vaccine recipient/caregiver that they should come back if there is any concerns or severe symptoms

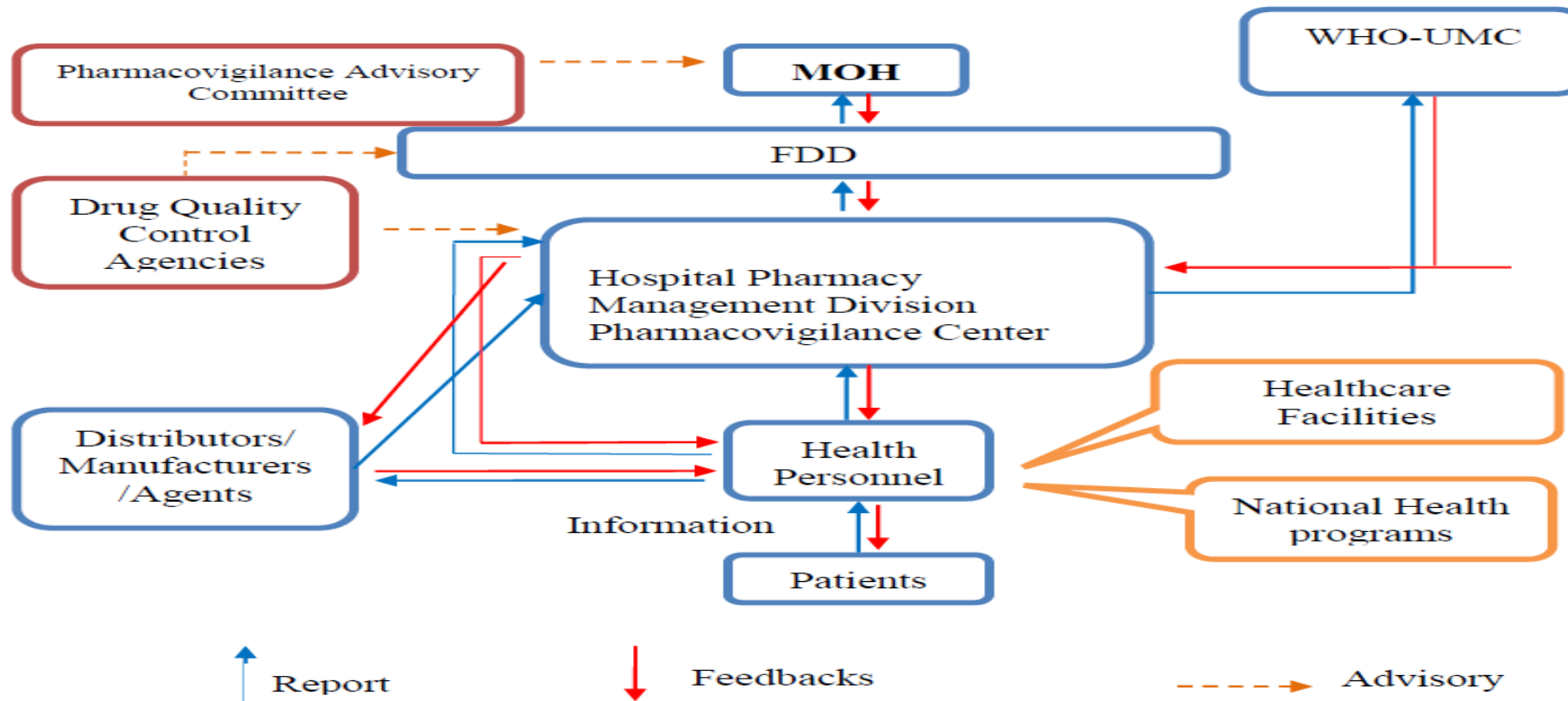
When you communicate with vaccine recipient/parents/caregiver of an AEFI case you should

- Listen empathetically to them and their concerns
- Reassure and support them but do not make false promises
- Assist with them for hospitalization, if needed
- Communicate frequently with the patient/caregiver regarding the progress of the patient
- Do not jump into conclusion that vaccine caused the event. Most of the serious AEFI cases are coincidental.

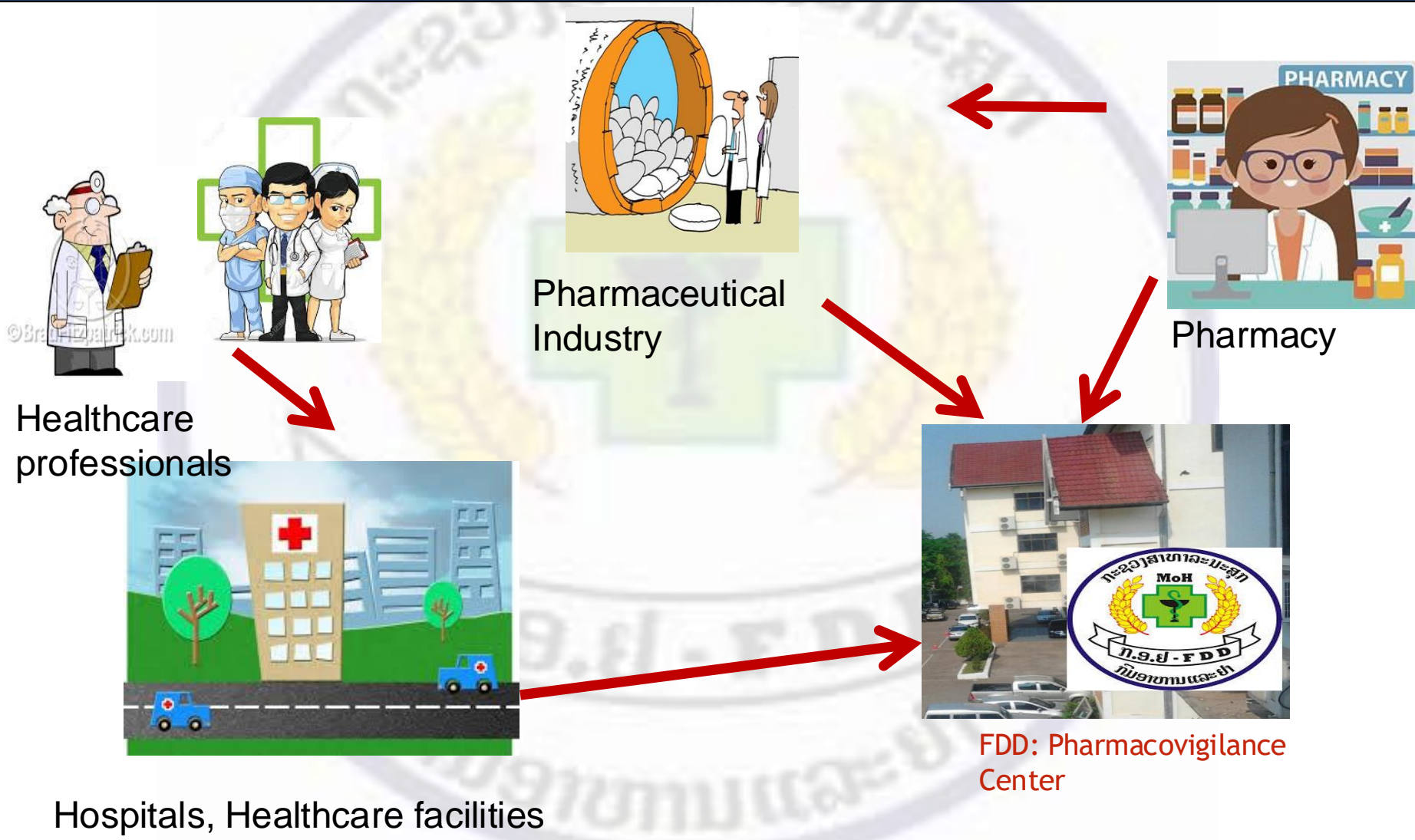
PHD will support local health facilities and is responsible of AEFI case investigation

- Immediately activate AEFI investigation team
- Investigate the event
- Send investigation report to the National level
- Communicate with parents/family/community

Reporting System



Report System



Healthcare professionals



Pharmaceutical Industry



Pharmacy



Hospitals, Healthcare facilities



FDD: Pharmacovigilance Center

ICSRs

Filter on drug, reaction, patient age, patient sex

Filter

Lao People's Democratic Republic Global view

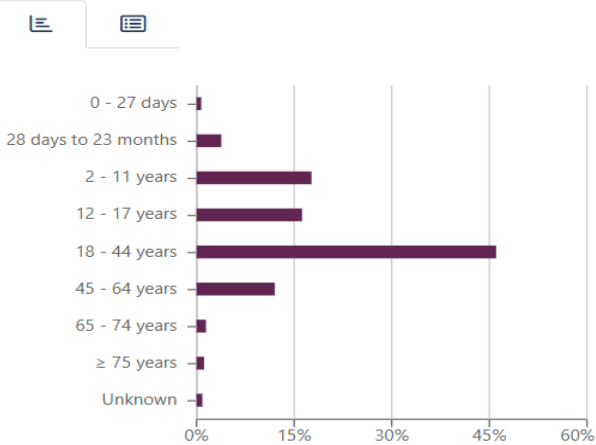
Country: Lao People's Democratic Republic

1 653 cases match your background

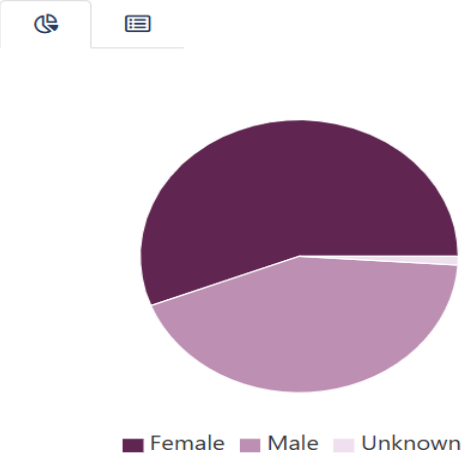
Overview Cases **f(*) Disproportionality** Related investigations (0)

Export

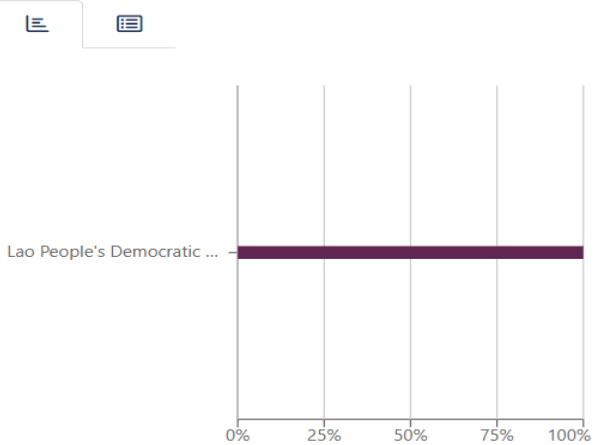
Patient age



Patient sex



Countries



ICSRs (cont)

Reported AEFI Cases - COVID-19 Vaccination



Add filter

More

AEFI - Total reported cases

258

AEFI - Total reported cases per 100K doses

1.9

AEFI - Reported serious cases

43

AEFI - Reported serious cases per 100K doses

0.3

AEFI - Reported non-serious cases

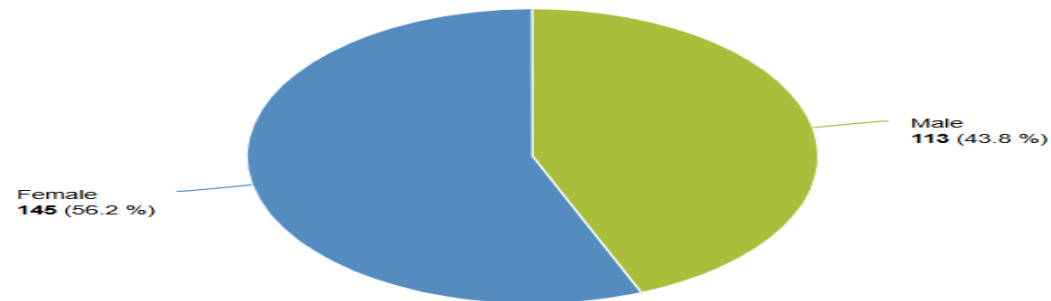
215

AEFI - Reported non-serious cases per 100K doses

1.5

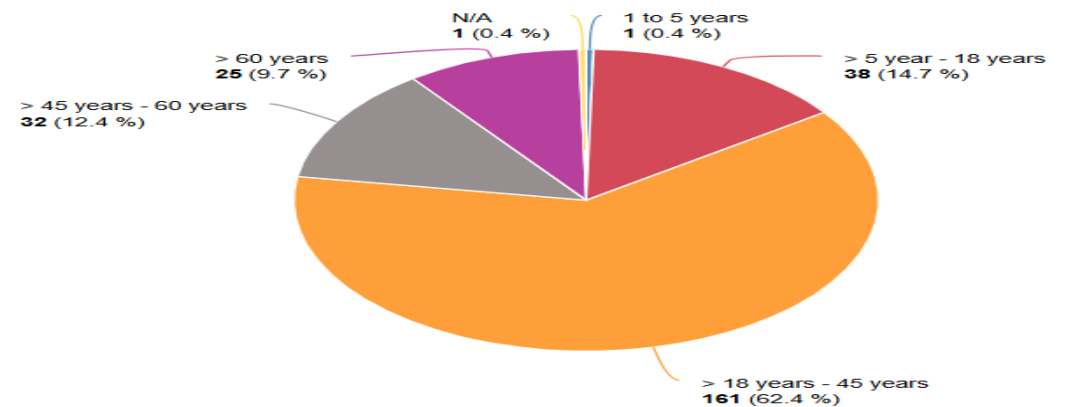
AEFI - Reported cases by sex

COVID-19 - 2024, 2023, 2022, 2021 - Lao PDR



AEFI - Reported cases by age group

COVID-19 - 2024, 2023, 2022, 2021 - Lao PDR










GBT Assessment 2023



World Health Organization

computerized Global Benchmarking Tool (cGBT)

Country	Scope	Date of visit	Tool's version	Type of visit	Status
Lao People's Democratic Republic	All	10.07.2023 - 14.07.2023	_GBT Rev VI, ver. 1 (E) _cGBT Ver. 13.22 last update Jun 2023	Self benchmarking	Draft

RS  01-NATIONAL REGULATORY SYSTEM (RS) Contains data: Yes Implementation Percentage 56	MA  02-REGISTRATION AND MARKETING AUTHORIZATION (MA) Contains data: Yes Implementation Percentage 56	VL  03-VIGILANCE (VL) Contains data: Yes Implementation Percentage 88
MC  04-MARKET SURVEILLANCE AND CONTROL (MC) Contains data: Yes Implementation Percentage 66	LI  05-LICENSING ESTABLISHMENT (LI) Contains data: Yes Implementation Percentage 58	RI  06-REGULATORY INSPECTION (RI) Contains data: Yes Implementation Percentage 53
LT  07-LABORATORY TESTING (LT) Contains data: Yes Implementation Percentage 92	CT  08-CLINICAL TRIAL'S OVERSIGHT (CT) Contains data: Yes Implementation Percentage 42	LR  09-NRA LOT RELEASE (LR) Contains data: Yes Implementation Percentage 0

Previous status of pv year 2023 assessed

← 03-VIGILANCE (VL)

- Executive Summary
- Strengths
- Verify Function

- Implemented (69.2%)
- Partially implemented (23.1%)
- Ongoing implementation (7.7%)
- Not implemented (0.0%)
- Not available (0.0%)
- Not applicable (0.0%)



Maturity level



Implementation



Import / Merge

Delete

By

Text	Category	ML	Status	Implementation	IDPs
▶ VL01 Legal provisions, regulations and guidelines required to define regulatory framework of vigilance.	01. Legal provisions, regulations and guidelines			89.0	5
▶ VL02 Arrangement for effective organization and good governance.	02. Organization and governance			100.0	1
▶ VL03 Human resources to perform vigilance activities.	06. Resources (HR,FR, infrastructure and equipment)			88.0	3
▶ VL04 Procedures established and implemented to perform vigilance activities.	07. Regulatory process			78.0	5

Challenges

- Inadequate quantity and quality of staff
- Limited capacity for information sharing among regional regulatory authorities
- Lack of IT infrastructure
- Language barrier for staff especially for assessors / enter data
- Lack of understanding on PV system by healthcare providers and stakeholders
- Lack of established guidelines and SOPs
- Coordination with NIP on AEFI report is still on process
- Financial constraints

Next Step

- Review law and regulation base on GBT assessment
- Revise PV guideline/Signal Detection guideline
- Develop SOP related to PV
- DHIS2 for AEFI and to upload data to VigiFlow
- Upgrade ADR reporting from paper-based system into electronic database
- Train and encourage private pharmacies on ADR reporting

*K
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C
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Thank you !

