Medicines Quality Monitoring Program 5 Year Report

Reporting period (2005-2009)

Supported by: USAID through USP DQI/PQM

Reported by the Food and Drug Department
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Acknowledgements

We would like to express our sincere thanks to the United States Pharmacopeia Drug Quality and Information (USP DQI) Program (now known as Promoting the Quality of Medicines or PQM), a program financially supported by the United States Agency for International Development (USAID) for its technical assistance provided to Ministry of Health’s Food and Drug Department (FDD), Food and Drug Quality Control Center (FDQCC), Medical Product Supply Center and Center of Malariology, Parasitology and Entomology (CMPE) since 2003 to improve the quality of medicines in Lao PDR.

We also wish to express our sincere appreciation and thanks Dr. Patrick Lukulay, Dr. Souly Phanouvong, Ms. Laura Krech, Mr. Christopher Raymond, Mrs. Nancy Blum, Dr. Abdel Karin Smine, Ms. Lisa Straker, Mr. Sanford Bradby and others from USP DQI/PQM, Dr. Krongthong Thimasarn from WHO, Dr. Paul Newton from Welcome Trust for their support and advice on training and operationalization of medicines quality monitoring of anti-malarial, antibiotics, anti-tuberculosis and retroviral over the past five years. The most important contributing factor leading to the project accomplishments has been persistent communication and close coordination among the implementing partners and USP DQI and individual staff work contribution. We also would like to express our special thanks to USAID/Regional Development Mission for Asia for their support through USP DQI/PQM to Lao PDR to improve the quality of anti-infective medicines and combat the counterfeit and substandard medicines.

Achievements and progresses of the project are a result of dedication and participation on the part of all involved staff from FDQCC, CMPE and FDD at central as well as provincial levels. Especially the following 12 Provincial Health Departments: Luangnamtha, Oudomxay, Xiengkhuang, Houaphan, Xayabouly, Luangprabang, Savannakhet, Khammouane, Champasack, Saravane and Attapeu, and Sekong.

On this occasion, we would like to highly thank to all whose names mentioned above for all your effort and effective cooperation and collaboration. We are confident that, after implementing this collaborative project during the past 5 years or so, we have gained good lesson in monitoring medicines quality in our country and used data to raise awareness on the danger of counterfeit and substandard medicines, and took regulatory enforcement actions according to our law and regulations. This work could not be achieved by working alone or a single institution/organization, as it requires multi-stakeholders’ involvement, coordination, communication and commitments at national and provincial levels.
Acronyms

ATP FDU  Attapeu Food and Drug Unit
CP FDU  Champasak FDU
CMPE  Center of Malariology, Parasitology and Entomology-Laos
DQI  Drug Quality and Information
FDD  Food and Drug Department
FDQCC  Food and Drug Quality Control Center
LNT FDU  Louangnamtha Food and Drug Unit
MOH  Ministry of Health
PHD  Provincial Health Department
MQM  Medicines Quality Monitoring
QA  Quality Assurance
CQ  Chloroquine
PQM  Promoting the Quality of Medicines Program
QC  Quality Control
SP  Sulfadoxine+Pyrimethamine
SNK FDU  Savannakhet Food and Drug Unit
SBL FDU  Sayabouly Food and Drug Unit
USAID  United Stated Agency for International Development
USP DQI  United States Pharmacopeia Drug Quality Information
WHO  World Health Organization
XK FDU  Xiengkhouane Food and Drug Unit
Project Summary

Since April 2003, the Medicines Quality Monitoring Program (MQM) has provided financial and technical assistance to Lao PDR through United State Pharmacopoeia Drug Quality and Information (USP DQI) in collaboration with the World Health Organization (WHO). The project aims to strengthen drug quality assurance programs and quality control systems at the national and program levels, with two primary objectives (1) to obtain evidence-based data from the field on the quality of selected anti malarial drugs in Lao PDR, and (2) to present recommendations to policy makers on developing and implementing appropriate strategies to address drug quality problems.

This project was started initially by training on the good laboratory practice (GLP), basic test (physical, visual inspections/examination), simple disintegration and thin-layer chromatography (TLC), sample collection and data reporting. In additions, from 2005-2009 the program has been extended to cover the issues on law enforcement, procurements and Good Manufacturing Practice. Twelve sentinel sites were recruited in the project implementation, started by three sentinel sites in 2003-2005, three more were selected in 2006, and than six more sentinel sites were added in 2007. The sites were selected based on four criteria: (1) their geographic location (bordering with neighboring countries), (2) their high level of drug resistance, (3) their high malaria prevalence and (4) the appearance of cross-border illegal trade in medicines. The testing methods used were 1. Physical characterized check for appropriate labeling, 2. Identify of active pharmaceutical ingredient(s) (API(s)), 3. Disintegration and 4. Content of API(s), 5. Weight variation. 6. Dissolution tests may be required.

The total number of samples collected from 2005-2009 was 1567, of these 18 samples were failed confirmatory testing. The number of samples increased from 158 in 2005 to 346 in 2009 due to the increase of number of sentinel sites. However, the percentage of samples that failed confirmatory testing reduced from 3.2% in 2005 to 0.6% in 2009. It was found that only anti-malarial and antibiotics were failed from standard from year 2005 to 2009 but none substandard and counterfeit tuberculosis and HIV/AIDS medicines were found. These substandard and counterfeit medicines were found to be available in 9 provinces, but not available in Sayabury, Xiengkhuang and Oudomxay. Most of the failed samples were found in private sector 16/18, and only 2/18 in public sector. The selected API of interest was artesunate, where the trend of counterfeit was fructuated from 2005-2009.

In order to strengthen the quality assurance, quality control and law enforcement in Lao PDR, financial and technical assistance from USP PQM should be continued including technical training for staff on analytical technique in order for them to gain better skills in analysis, and to assure the accuracy and precision of results. In addition, the cooperation, collaboration among central, local levels and relevant institutions, police, trade and customs should be enhanced. Furthermore, monitoring of drug quality in pharmacies in all provinces throughout the country should be performed regularly. Strong measures should be taken in the case of violations.
Background

The Lao People’s Democratic Republic (Lao PDR) is a land-locked country with the area of 236,800 square kilometres and 5.6 million of population (2005). It is located in the Indochinese Peninsula, sharing border with Vietnam, Thailand Cambodia, China and Myanmar. It is one of Great Mekong Sub-region Countries (GMS). The most population is living in rural areas (about 73%). Administratively, the country is divided into 17 provinces, 140 districts and 10,559 villages.

The health system consists of 4 levels: Central, Provincial, District and Village Level. In the public sector there are 6955 health facilities: 4 central hospitals, 4 regional hospitals, 12 provincial hospitals, 127 district hospitals, 874 health centers, and 5934 drug kits. In the private sector, there are 1964 private pharmacies where dispensing of medicine has been taken place.

With financial and technical assistance by USAID through United State Pharmacopoeia Drug Quality and Information (USP DQI) in collaboration with the World Health Organization (WHO), the Medicines Quality Monitoring Program (MQM) started in April 2003 in Lao PDR, aiming at strengthening capacity building of health staff on basic knowledge of medicine testing at the provincial and central levels. This project was started initially by training on the good laboratory practice (GLP), basic test (physical, visual inspections/examination), simple disintegration and thin-layer chromatography (TLC), sample collection and data reporting. In additions, from 2005-2009 the program has been extended to cover the issues on law enforcement, procurements and GMP.

The project has been performing 11 rounds of collection and testing samples. The MQM has already covered 12 provinces (Luangnamtha, Oudomxay, Sayabouly, Louangprabang, Xiengkhouang, Huanphnh, Savannakhet, Kham mouane, Champasak, Saravanh, Attapeu and Sekong Provinces), where malaria, tuberculosis and HIV/AIDS are the most prevalence, as well as substandard and counterfeit medicines.

From 2003-2005, 3 sentinel sites: Sayabouly, Savannakhet and Champasak provinces were first included in the project. In 2006, it has been expanded to three more sentinel sites /3 Minilabs: Luangnamtha, Xiengkhuan and Attapeu provinces. In 2007, the project has expanded to cover 6 more provinces sharing borders with existing sentinel sites such as Houaphan, Oudomxay, Luangprabang, Kham mouane, Saravane and Sekong provinces.

The morbidity and mortality rate in Lao PDR is still high compared with other countries in the region, although much improvement in health care has been made from the last ten years. Malaria, tuberculosis and HIV/AIDS are among the main cause of morbidity and mortality. The Use of Substandard and counterfeit medicines will be harmful to health. It may cause ineffective treatment of diseases or even death, thus contributing to the high morbidity and mortality.
Previously, there were several organizations supported in Quality Monitoring of Medicines especially medicine sampling and testing, such as Swedish International Cooperation Development Agency (Sida), UNICEF and Wellcome Trust. It was found that the quality of medicines has been improved from time to time. The substandard medicine has been gradually reduced, from 40% in 1996 to 20% in 1999, 32-35% in 2002 and 17% in 2003. Also the counterfeit medicines reduced from 5.9% in 2002 to 0.87% in 2003.

After the MQM program implementation, from 2003 to 2009 the quality of medicine has even been improved, characterized by the reduction of failed samples from 3.2% in 2005 to 0.6% in 2009. (For the detail please see table 1).

The inspections of pharmacies have been conducting regularly by FDD/PFDU at least twice a year. The FDU inspectors have monitored and inspected through distributors chain (company, factory, and pharmacy) following the regulation number 482/MOH on Governing of Pharmacy. The pharmacies have been checked expired drug, banned drug, unregistered/drugs without correct bill, and drugs with unlabelled package.
The medicines quality monitoring program has been regularly implemented since 2003, from 2005 to 2009, 11 round of the MQM program had been performed. 1567 medicine samples (20 items) have been sampled and tested. 18 failure medicines were found (10 counterfeit and 8 substandard medicines)

**Objective of the MQM**

**Main objectives**

Drug quality monitoring aims to strengthen drug quality assurance programs and quality control systems at the national and program levels. There are two primary objectives:

1. To obtain evidence-based data from the field on the quality of selected anti malarial drugs in Lao PDR.
2. To present recommendations to policy makers on developing and implementing appropriate strategies to address drug quality problems.

**The specific objectives are as follow:**

1) To perform the monitoring of anti-malarial medicines quality by using rapid, inexpensive, simple method.
2) To upgrade knowledge and skills of health staff (FDD, FDQCC, and CMPE) at national and provincial levels in sample collection, analysis using Mini-lab, data management and reporting.
3) To strengthen the capacity of FDQCC and 6 Mini-Lab in performing analysis
4) To improve the quality of anti-malarial medicines
5) To reduce substandard and counterfeit drug.
6) To strengthen collaboration and cooperation with relevant institutions as well as among Mekong sub-region countries for proper regulatory actions against counterfeit/substandard drugs.

**Methods**

1. **Criteria for selection of the sites:**

   The sites were selected (1) for their geographic location (bordering with neighboring countries), (2) their high level of drug resistance, (3) their high malaria prevalence and (4) the appearance of cross-border illegal trade in medicines.
2. Selection of the sites

2003-2005: 3 provinces/sentinel sites were selected:

1. Sayabouly Province: It is located at the North-Western part of the country. It consists of 10 districts, 495 villages and a total population of 362,200 as of 2003. There are 86 registered drug stores.

2. Savannakhet Province: It is located at the Southern part of the country. It consists of 15 districts, 1,542 villages and a total population of 833,900 as of 2003. There are 147 registered drug stores.

3. Champasack Province: It is located at the Southern part of the country. It consists of 10 districts, 942 villages and a total population of 622,400 as of 2003. There are 215 registered drug stores.

2006: Expanding more 3 provinces/sentinel sites as follow:

1) Luangnamtha Province
   It is located at the North-Western part of the country. It consists of 05 districts, 401 villages and a total population of 142,400 as of 2003. There are registered 27 drug stores.

2) Xiengkuang Province
   It is located at the North-Eastern part of the country. It consists of 7 districts, 537 villages and a total population of 249,000 as of 2003. There are 72 registered drug stores.

3) Attapeu Province
   It is located at the Southern part of the country. It consists of 5 districts, 211 villages and a total population 108,300 as of 2003. There are 22 registered drug stores.

2006 The project has expanded to cover 6 more provinces sharing borders with existing sentinel sites such as Houaphan, Udomxay, Luangprabang, Khammouane, Saravane and Sekong provinces.
3. The sampling team/ sample collection

- The composition of the “sampling team” consisted of:
  - National Lab/FDQCC
  - Food and Drug Department (FDD)
  - Provincial Food and Drug Unit

- Sample collection: staff followed the sampling procedure as described in the course materials. Each sample collected had “Drug sampling receipt form” properly filled out and attached to/inserted in to the sample container. Sample was kept and stored according to storage conditions required on the labels. Drug that has no “identifiable” name was not collected.

- Samples were collected from both public and private channels and as follow:
  - 2-3 hospitals health centers and clinics per collection round
  - 2-3 pharmacies per collection round

- Sample size (number of units/sample)
  * Minimum 30 for tablet or capsule dosage form
  * Minimum 50 for tablet or capsules for fixed-dose combination preparations.
  * 10 for indictable.
Number of sample:
Every effort has been made to collect at least five samples for each product per sentinel site per collection round. In the subsequent round of sampling, if a specific drug product of the same lot/batch number is found at the same location, there is no need to collect this product again unless some unusual labeling, packaging, expiry date, manufacturing date or physical characteristics of the product are observed.

Sampling technique and location: A convenient sampling method is used in this project. In the effort to obtain geographically as well as drug-wise representative samples, sampling locations have been identified based on the following principles:
1) Sectors coverage-sampling locations included in this project cover both the public and private sector supply and distribution systems, and both formal and informal channels
2) Geographical coverage both urban/suburban and rural areas of the sentinel sites selected.
3) Main route/flow of drug supply or distribution both from neighboring country and provinces.
4) Anti-malarial drug-wise coverage-common anti-malarial drugs and preparations from different brands/sources of manufacture and lots/batches are sampled.

Sampling records: A written record of the sampling operations carried out is shown in this form must be filled out and signed by all parties involved.

4. Testing Methods

At the sentinel site level:
Basic testing at the sentinel site level: testing methods and procedures described in the USP DQI Training manual and the reference substances/product provided by USPDQI including those provided with the GPHF-Mini lab kits should be used. The test cover:
- Physical/visual inspection/Examination
- Simple disintegration
- TLC
At the National and reference laboratory (FDQCC):
Verification and confirmation tests:
1. Physical characterized check for appropriate labeling.
2. Identify of active pharmaceutical ingredient(s) (API(s))
3. Disintegration and
4. Content of API(s).
5. Weight variation.

Testing procedures and assay method will be carried out according to the latest edition of
and International Pharmacopeia (IP), and/or USP/NF and/or other leading pharmacopeias.
The reference materials, substances and/or standards sources where possible and appropriate,
are from IP and USP reference standards. Other reference materials or substances or products
can be used.

Results

The total number of samples collected from 2005-2009 was 1567; of these 18 samples were
failed confirmatory testing. The number of samples increased from 158 in 2005 to 346 in 2009
due to the increase of number of sentinel sites. However, the percentage of samples that failed
confirmatory testing reduced from 3.2% in 2005 to 0.6% in 2009 (table 1). It was found that only
antimalarials and antibiotics were failed from standard from year 2005 to 2009 but none
substandard and counterfeit tuberculosis and HIV/AIDS medicines were found (table 2). These
substandard and counterfeit medicines were found to be available in 9 provinces, but not
available in Sayabury, Xiengkhuang and Oudomxay (table 3). Most of the failed samples were
found in private sector 16/18, and only 2/18 in public sector (table 4). The selected API of
interest is artesunate, where the trend of counterfeit is fluctuated from 2005-2009 (Graph 1-2).

Table 1: Total number of samples collected and tested by year and the failure rate

<table>
<thead>
<tr>
<th>Year</th>
<th>Total No. of samples tested of all medicines (anti-malarial, anti-TB, HIV/AIDS, antibiotics and AI combined)</th>
<th>No. of samples that passed testing (basic testing and confirmatory testing)</th>
<th>No. of samples that failed confirmatory testing Number / (% failed)</th>
</tr>
</thead>
<tbody>
<tr>
<td>2005</td>
<td>158</td>
<td>153</td>
<td>5 / 3.2%</td>
</tr>
<tr>
<td>2006</td>
<td>301</td>
<td>297</td>
<td>4 / 1.3%</td>
</tr>
<tr>
<td>2007</td>
<td>407</td>
<td>402</td>
<td>5 / 1.2%</td>
</tr>
<tr>
<td>2008</td>
<td>355</td>
<td>353</td>
<td>2 / 0.6%</td>
</tr>
<tr>
<td>2009</td>
<td>346</td>
<td>344</td>
<td>2 / 0.6%</td>
</tr>
</tbody>
</table>
FDQCC and Provincial Health staffs performed sample collection at Pharmacy in Luangprabang Province

Samples collection in Sayabouly

Samples collection in Sekong

Table 2: Summary of samples collected and tested by therapeutic indication and year

<table>
<thead>
<tr>
<th>Therapeutic Indication</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Results</td>
<td>Test Results</td>
<td>Test Results</td>
<td>Test Results</td>
<td>Test Results</td>
</tr>
<tr>
<td></td>
<td>Total # samples tested</td>
<td>Total # sample passed testing</td>
<td># and % of sample tested</td>
<td>Total # sample tested</td>
<td>Total # sample passed testing</td>
</tr>
<tr>
<td>AMLs</td>
<td>113</td>
<td>108</td>
<td>5 / 4.4%</td>
<td>69</td>
<td>69</td>
</tr>
<tr>
<td>ATBs</td>
<td>19</td>
<td>19</td>
<td>0%</td>
<td>22</td>
<td>22</td>
</tr>
<tr>
<td>ARTs</td>
<td>45</td>
<td>45</td>
<td>0%</td>
<td>213</td>
<td>209</td>
</tr>
<tr>
<td>AI</td>
<td>3</td>
<td>3</td>
<td>0%</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>HIV/AIDS</td>
<td>3</td>
<td>3</td>
<td>0%</td>
<td>3</td>
<td>3</td>
</tr>
</tbody>
</table>
Table 3: Table of sites where poor quality medicines were found most frequently

<table>
<thead>
<tr>
<th>Site</th>
<th>2005 Description</th>
<th>2006 Description</th>
<th>2007 Description</th>
<th>2008 Description</th>
<th>2009 Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attapeu</td>
<td>1 counterfeit (artesunate)</td>
<td>2 substandard (Vactrime)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sekong</td>
<td></td>
<td></td>
<td></td>
<td>1 substandard (methronidazole)</td>
<td></td>
</tr>
<tr>
<td>Savannakhet</td>
<td>1 substandard (Chloroquine)</td>
<td>1 substandard (amoxicillin)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Khammouane</td>
<td></td>
<td>1 counterfeit (artesunate)</td>
<td></td>
<td>1 counterfeit (artesunate)</td>
<td></td>
</tr>
<tr>
<td>Champasack</td>
<td>1 counterfeit (artesunate)</td>
<td></td>
<td></td>
<td>1 counterfeit (artesunate)</td>
<td></td>
</tr>
<tr>
<td>Saravan</td>
<td></td>
<td>1 counterfeit (artesunate) and 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>substandard (erythromycin)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Luangprabang</td>
<td></td>
<td></td>
<td></td>
<td>1 counterfeit (ampicillin)</td>
<td></td>
</tr>
<tr>
<td>Luangnamtha</td>
<td>1 substandard (ampicillin)</td>
<td>1 counterfeit (artesunate)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Houaphanh</td>
<td></td>
<td>1 substandard (methronidazole)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 4: Summary of total test results by sector (public, private and informal).

<table>
<thead>
<tr>
<th>Sector</th>
<th>2005</th>
<th>2006</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Test Results</td>
<td>Test Results</td>
<td>Test Results</td>
<td>Test Results</td>
<td>Test Results</td>
</tr>
<tr>
<td></td>
<td>Total # sample tested</td>
<td>Total # sample passed testing</td>
<td># and % of sample failed testing</td>
<td>Total # sample tested</td>
<td>Total # sample passed testing</td>
</tr>
<tr>
<td>Public</td>
<td>23</td>
<td>22</td>
<td>1 / 4.4 %</td>
<td>64</td>
<td>64</td>
</tr>
<tr>
<td>Private</td>
<td>135</td>
<td>131</td>
<td>4 / 3.0 %</td>
<td>237</td>
<td>233</td>
</tr>
<tr>
<td>Informal</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Drug analysis at Food and Drug Quality Control Center
Graph 1: Trend of counterfeit Artesunate 2005 - 2009

**Artesunate**

Graph 2: Trend of counterfeit Artesunate (2005-2009)

Graph 3: failure medicines were found most frequently (2005-2009)
Graph 4: Overall Failure vs Pass Rate (2005-2009)

Overall pass rate 98%

Overall substandard rate 1%

Overall counterfeit rate 1%

Discussion

**Sampling method and technique:** The convenience sampling technique was used for sample collection which could be a source of bias and the data can not be representative. The “Drug sampling receipt form” used for collecting information on drug sample had to be signed by drug seller at the end of collection, this made drug seller aware that the data collector is drug inspector or regulator, when the team visited the next pharmacies the sellers had already been informed about our arrival. In this case, the sellers might hide the counterfeit and substandard medicines.

**Testing results:** There has been a remarkable reduction of substandard and counterfeit antimalarials and antibiotics from 2005 to 2009. However, substandard and counterfeit medicines are still a problem. The trend of counterfeit artesunate was fluctuated.

**Action taken:**

In the case of substandard and counterfeit found, investigation has been made. Some measures were performed in accordance with the Law on Medicine and Medicinal Product and regulation number 482/MOH on Governing of Pharmacy. The PFUD were persistent and active about implementing rules and regulations against violators, especially in cases of counterfeit, expired, and banned products found in the pharmacy, and non-compliance to the “10 Indicators.” The following actions have been taken when the counterfeit and substandard medicines were confirmed from the laboratory.

1. The FDD issued announcements to all Provincial Health Departments (PHD) especially Provincial Food and Drug Unit (PFDU) regarding the lot/batch number of counterfeit or substandard medicines, the name of pharmacies where the counterfeit was found, and suggested action to be taken following the Standard Operation Procedure (SOP) developed by FDD. The PFDU inspectors conduct the inspection at both public and private pharmacies and take action according to law and regulation.
2. The FDD also issued announcements informed to all provinces in case received alert announcement from ASEAN or WHO.
3. The FDD also advertised the counterfeit medicines through different media e.g., newspapers, radio and National TV and posters. (Veintianemai, Vientianetimes and Pasasone Newspapers…)

4. Organized meeting with relevant institutions such: as customs and trade to discuss and find the way to tackle the problems.

5. Organized meeting at province by FDD staff collaborated with FDU and relevant local authorities: police, customs and trade to discus and find out together the solution. At the same time the violated sellers were punished in the form of warning and fine by inviting them to the meeting at the FDU.

6. Punishments of private providers have been made, for examples: in 2009, fines of about 90,000,000 kip were deposited to FDD in the case of counterfeit tanganil, and in 2008, 4,500,000 kip in the case of counterfeit Ampicilline. In Mach 2008,

7. In Xiengkhouang FUD conducted sanctions against six non-compliance retail pharmacies by suspending their licenses and seized expired pharmaceutical products worth 2000 USD and disposed of them in April 2009.

8. In Champasak Province, the Champasak FDU confiscated 39 items of expired and illegal medicines and ports of entry and disposed.

9. Illegal imported Artesunates were destroyed in total of 2030 ampoules which amounted to 1,015 USD.

| 1. Sample of an announcement issued by FDD to PFDU | 2. List of pharmacies where failure medicines found attached with announcement from FDD | Alert from ASEAN, FDD announce to all provinces |

| ![Image](image1.png) | ![Image](image2.png) | ![Image](image3.png) |

FDD organized meeting with relevant authorities
<table>
<thead>
<tr>
<th>Meeting in Sayabouly Province</th>
<th>Meeting at Champasak FDU</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image1" alt="Meeting in Sayabouly Province" /></td>
<td><img src="image2" alt="Meeting at Champasak FDU" /></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Meeting in Saravan Province</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image3" alt="Meeting in Saravan Province" /></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Counterfeit Artesunate 50mg advertised on newspaper in 2008</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image4" alt="Counterfeit Artesunate 50mg advertised on newspaper in 2008" /></td>
</tr>
</tbody>
</table>
Counterfeit Ampicilling 500 mg found 2009

Tanganil found in 2009 were destroyed

Additional achievements in relation of capacities building for FDD, FDQCC and MPSC
Additional accomplishments from 2005 to 2009 are as the following:

**For FDQCC:**
- Organized a training course on basic knowledge on GLP, medicines sampling and quality data management, disintegration, HPLC in 2006.
- 3 participants attended in training course on GLP, Dissolution, HPLC and analysis for Artesunate in Bangkok, Thailand.
- 3 staffs of FDQCC participated in training course on advance testing of Tuberculosis in Bangkok, Thailand in 2009.
- The project provided support on the procurement of chemicals, glassware and reference standard every year. In addition, some furniture and office equipments have been provided to FDQCC and six sentinel sites for improving their working condition.

**For Food and Drug Department:**
- USP DQI organized GMP inspection training course at FDD including site inspection Coduphar-Lao Factory in 2006.
- Budget was supported to develop manual for GMP inspection of Laos.
- 5 GMP inspectors attended the training course on GMP at Mahidol University, Thailand in 2009.

**MPSC:**
- In year 2006, supported Mittaphab Hospital to improve working condition for dispensing area, and conduct two training courses on hospital pharmacy management for 3 hospitals: Mahosot, Setthatilat and Mittaphab. In addition, the project provided budget for develop training materials on GDP and GPP and printing as manual.
- Conducted training workshop on Medicines Quality Assurances, Good Practices for the procurement, distribution, storage and distribution of pharmaceuticals with focused on Anti retroviral medicines in Savannakhet Province. The training on Good Dispensing Practice was conducted at MOH, with participation of representative from MPSC, FDD, FDQCC, Mittaphab, Setthathilath, Mahosot and Mother and Child Hospital, Health Science University.
- In 2008, USP DQI continued to support for improving condition of dispensing system of Mittaphab Hospital, organized training workshop on Quality, Safety and Rational use of HIV/AIDS medicines at MPSC.

**Key Observations and Recommendations**

- At the country level, coordination between the country and PQM has been implemented with a satisfactory result in terms of funding, reporting and others. However, some challenges have been observed as the following:
  ♦ Knowledge and skills of some staff on analytical technique are limited.
  ♦ Data reporting system of analysis is not fairly complete in some province (Attapeu)
  ♦ Facilitating conditions for the Lab are insufficient (furniture, computer, glass wares) stationary, material for laboratories.
  ♦ Trained staff have been moved to other work
  ♦ Financial and managerial skills of staff in project management need to be strengthened
Lessons learned

♦ The link between the improvement of quality of medicines and the reduction of morbidity and mortality rate of malaria has been observed during the last five years.
♦ The success of the implementation of the project depended on:
- Close and regular supervision and advice by high ranking leaders of Ministry of Heath is crucial for the success of the project.
- Good Cooperation between central, provincial and district levels and collaboration with relevant institutions are the key for the effectiveness of the implementation.
- Highly responsibilities of staff on performance of their tasks are important.
- The implementation of activities was unified among related parties.
- Technical and financial assistance by the international organization (USPDQI).

Recommendations

- Technical training for staff on analytical technique should be continued in order for them to gain better skills in analysis, and to assure the accuracy and precision of results.
- The facilitating conditions for the FDQCC as well as provincial laboratories with Mini-Lab should be continued to supplied, such as: materials for laboratories and offices so that they can be further strengthened.
- Cooperation, collaboration among central, local levels and relevant institutions, police, trade and customs should be enhanced.
- Monitoring of drug quality in pharmacies in all provinces throughout the country should be performed regularly. Training on Good Pharmacy Practice should be provided to drug sellers so that they can contribute to tackle the problem of counterfeit and substandard drugs.
- Training on Good Manufacturing Practice (GMP) for local producers should be provided as well as Good Wholesaling practice (GWP) for importers, to avoid counterfeit and substandard drugs.

In order to strengthen regional and international collaboration to address the medicines quality issues and problems, the following suggestions should be considered:

1) Strong cooperation between countries involving in the USP PQM project to exchange lessons, expertise, data information to lead the project in achieving the setting goals.
2) Financial and technical assistance from USP PQM should be continued and increased so that the project can be implemented 2 rounds per year for sample collection of anti-malarial, antibiotic, anti tuberculosis and antiretroviral drugs.
3) Support counties to attend training and workshop on quality control and GMP within the region.

Conclusions

After implementing the anti-malarial, antibiotics, anti tuberculosis and anti retroviral drug quality monitoring project supported by USPDQI/PQM in the past 8 years it could be seen that the project has been progressively succeed which can be briefed as the followings:
1) Establish capacities in drug testing to the FDQCC and 6 provincial laboratories: Luangnamtha, Xayabouly, Xiengkhuang, Savannakhet, Champasack, Attapeu by providing equipments, chemical, reference standards and facilitating conditions (furnitures, computer, air conditioners…).

2) In the period of 5 years (2005-2009), sample collections have been carried out in 12 provinces: Luangnamtha-Oudomxay, Xiengkhuang-Houaphan, Xayabouly-Luangprabang, Savannakhet-Khammouane, Champasack-Saravane and Attapeu- with the total number of 1567 samples including 20 drug items, the basic tests were performed at 6 Mini-Labs and verifications by pharmacopea at the FDQCC. From the test results, there were 10 counterfeit (9 Artesunate, 1 Ampicilline) and 8 substandard drugs (1 Chloroquin, 2 Vactrim, 1 Amoxicillin, 1 Ampicillin, 1 Erythromycin, 2 Methronidazol).

3) A technique used by basic tests (Mini-Lab) is simple-to-do, rapid, inexpensive, suitable for application in developing countries and technical staff is able to utilize easily as well.

4) During drug quality monitoring at pharmacies, health centers, and clinics, technical staff has the opportunity to give advices to the drug sellers which contribute to better improvement of pharmacies.

5) Collected samples and testing results on the drug quality were regularly reported to the relevant authorities and high ranking officers who can be used to improve, develop more appropriated policies and strategies.

   - A part from this, counterfeit and substandard drugs were addressed by stated regulation and laws.

**Next steps**

Country’s strategic goals and objectives to improve the quality of essential medicines are:
- Strengthening Quality Assurance System including quality control, marketing authorization, local manufacturing and procurement.

List priority areas of medicine QA/QC needs to address in the next 2-3 years:
- Medicine samples collection and testing.
- Procurement of chemical reagent, reference standard, glassware.
- Training on ISO 17025, GLP and Laboratory Management.
- Establishment ADR system monitoring.
- GMP improvement
- Strengthening capacity building for students at the Faculty of Pharmacy, Health Science University by providing some necessary equipment to the laboratory.

**Describe the framework to implement the above strategies.**

1. Continue building the capacity of Food and Drug Department (FDD) and Food and Drug Quality Control Center (FDQCC) in addressing the problems of substandard and counterfeit medicines through establishing and maintaining and effective anti infective medicines quality monitoring, and support to strengthen FDQCC’s capacity analyses:
   - Samples purchase and collection for anti malarial, anti-tuberculosis medicines (both 1st and 2nd lines that have testing method for), ARVs and
selected antibiotics by the sample collecting team. The sample collection should be beyond the existing sentinel sites to all border provinces and Vientiane Capital as new sentinel site

- Reference substances, chemical products and necessary supplies for the Minilab testing to the 6 sentinel sites Labs and confirmatory testing at FDQCC
- Improvement of working conditions at 6 sentinels site.
- Updating knowledge of analysts, GLP, ISO 17025 for FDQCC staffs and FDU staffs inside and outside country.

2. Improving the existing regional labs in three provinces: Luangprabang, Savannakheth and Champasak.

3. Strengthening the capacity of Food and Drug Department in post-marketing surveillance, regulatory enforcement and awareness raising:
   - Project administration, communication, and reporting between the PMT and USP DQI and FDD other relevant agencies, including PMT meeting, report.
   - Establishing ADR system.
   - Strengthening capacity Lao GMP inspectors by participating GMP inspection training course in some countries.

4. Strengthening the good coordination provide among concerned stakeholders in combating against counterfeit and sub-standard medicines.

5. Strengthening capacity building for students at the Faculty of Pharmacy, Health Science University.
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