Joint Regional Training Workshop on Surveillance and Reporting of Substandard/ Spurious/ Falsely Labelled/ Falsified/ Counterfeit (SSFFC) Medical Products

Report of the regional training workshop
Jakarta, Indonesia
9-12 October 2016
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Disclaimer

This training workshop and report were made possible by the joint efforts and support of the Asian Development Bank (ADB), United States Agency for International Development (USAID), United States Pharmacopeial Convention (USP) Promoting the Quality of Medicines Program (USP-PQM), World Health Organization (WHO) and Badan POM. The contents are the responsibility of the authors and do not necessarily reflect the views of the ADB, Badan POM, USP, USP-PQM, or WHO.
Executive summary

Given the dangers and public health threats in South-East Asia of substandard/ spurious/ falsified/ falsely-labelled/ counterfeit (SSFFC) medical products and their potential contribution to the drug resistance such as artemisinin-resistant malaria in the Greater Mekong Sub-region and South-East Asia in general, a regional training workshop was held to raise awareness of the need for SSFFC surveillance and information-sharing in the WHO South East Asia Region among national regulatory authorities (NRAs). The workshop was convened under the auspices of the World Health Organization (WHO) with technical input from the United States Pharmacopeial Convention (USP). It was supported by the Asian Development Bank (ADB), the United States Agency for International Development (USAID) through the USP Promoting the Quality of Medicines program (PQM) and the National Agency of Drug and Food Control in Indonesia (Badan Pengawas Obat dan Makanan; Badan POM). Eleven countries (Bangladesh, Bhutan, India, Indonesia, Maldives, Myanmar, Nepal, Papua New Guinea, Sri Lanka, Thailand, Timor-Leste) sent delegates. The objectives of the workshop included strengthening NRA capacity to prevent, detect and respond to SSFFC medical products, developing awareness of the need for robust post-market surveillance and reporting in order to protect public health, improving knowledge of laboratory support, field detection technologies and effective sampling methodologies and identifying and training nominated country NRA focal persons in the use of the WHO global surveillance and monitoring rapid alert system for reporting SSFFC medical products.

Over the three days of the interactive workshop, participants were introduced to the global scale and public health threats and impact of SSFFC medical products, and how the WHO rapid reporting scheme could support the work of NRAs. Delegates were presented with real cases and worked collectively to identify essential elements of information for investigation and reporting and to upload data using the WHO web portal. The USP supported this with sessions on regional laboratory development and accreditation, use of field detection equipment, sampling strategies and plans for effective post-marketing surveillance, and the importance of good distribution practice and supply chain integrity. The difficulties of dealing with internet trade of SSFFCs was also specifically addressed.

The workshop objectives were met with awareness and knowledge of SSFFC medical products and means to prevent, detect and respond to them increased among regulators. NRA focal points for the WHO surveillance and monitoring system were identified and trained and participants were made aware of laboratory and field detection technologies to support SSFFC activities. In a self-assessment, the proportion of respondents reporting good or high skills increased by between 47% and 73% on all domains. Reporting to the WHO surveillance and monitoring system from the region will also be assessed after six months. Follow-up of focal persons and engaging with high-level officials within the respective NRAs to implement and provide operational support for SSFFC surveillance and reporting will be critical to achieve long-term outcomes.

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1 In 2016, a WHO technical working group recommended that the WHO replace its use of the current terminology SSFFC with the simpler ‘substandard and falsified’ (SF). WHO will continue to use SSFFC until its member states come to a consensus.
List of Acronyms

ADB  | Asian Development Bank
ASEAN | Association of South East Asian Nations
Badan POM | Badan Pengawas Obat dan Makanan (National Agency of Drugs and Foods Control)
GMS  | Greater Mekong Subregion
NRA  | National regulatory authority
PQM  | Promoting the Quality of Medicines Program
RAS  | Rapid Alert System
SSFFC | substandard / spurious / falsely-labelled / falsified / counterfeit
USP  | United States Pharmacopeial Convention
WHO  | World Health Organization

Acknowledgements

The authors would like to thank the WHO, USP, USP-PQM, Badan-POM and ADB for the support they provided towards holding the workshop. The support of member states in sending their delegates to participate in the training is also acknowledged. Gratitude is also particularly due to the staff of USP-PQM Field Office Indonesia, Badan POM, ADB and WHO that contributed to the successful organisation of the meeting.
Background
Medicines that are substandard / spurious / falsely-labelled / falsified / counterfeit (SSFFC) are a risk both to individual and public health. Their presence in the market undermines the patients’ right to safe, effective, quality medicines, they can contribute to increased morbidity, mortality and health care costs since they are usually ineffective and sometimes toxic, and they decrease confidence in health systems and effective treatments. Furthermore, they contribute to increased antimicrobial resistance since microbes and parasites are exposed to subtherapeutic doses of active ingredient(s). This is of particular concern with regard to malaria and artemisinin resistance in the Greater Mekong Subregion (GMS) and South East Asia as well as being relevant to other communicable diseases like tuberculosis. Regulatory strengthening and increased surveillance to detect and eliminated SSFFCs from the market have been identified as key activities in the Malaria Elimination Strategy for the Greater Mekong Subregion.2

Little is known of the global scale of the problem since there has been no systematic collection of data. However, in a multi-country survey in Cambodia, Laos, Myanmar and Thailand in 2003, 53% of products containing artesunate were found not to contain any active ingredient.3 A 2010-2011 cross-border study in Cambodia suggested a failure rate of 12% (n=46 of 374 samples).4 More recently, 13% of antimalarial medicines sampled in Cambodia were found to be substandard.5 Inadequate border controls and regulatory capacity constraints, particularly in remote areas, mean that these products are likely to be moving across borders, affecting more than a single country. In addition, increased internet access has increased the spread of SSFFC medicines and other health commodities across borders. This requires a collaborative approach towards surveillance and information sharing on SSFFCs in order to take effective action to protect public health from these products.

The WHO SSFFC surveillance and monitoring project rapid alert system (RAS) for reporting and monitoring SSFFCs provides a means for countries to report SSFFCs, a central risk assessment linking to other reports and coordinated sharing of information and action. The database also provides evidence to guide market surveillance, develop laboratory tests and identify those medicines most at risk. A regional mechanism to encourage NRAs to share and report the information on SSFFCs in a timely fashion to support joint investigation and enforcement action has been established since 2013 with technical assistance of PQM.6 However, reporting on SSFFCs from Asian countries through this mechanism and WHO RAS is generally weak. Given the challenge of SSFFC antimalarial products in the region, it is important that this RAS be strengthened in the region to complement regulatory capacity development and support for post-marketing surveillance activities. This activity was prioritised in the work plan of the Member State Mechanism on SSFFCs. At the third meeting of the

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6 This mechanism is called BREMERE, Build Regional Expertise in Medicines Regulation, Information Sharing, Joint Investigation, and Enforcement.
Member State Mechanism on SSFFCs, the value of the WHO Global Surveillance and Monitoring Project was recognised and it was recommended that it be expanded to all regions.7

Adequate laboratory capacity and support is linked to the identification and reporting of suspected SSFFC medical products. The United States Pharmacopeial Convention Inc. (USP) through its Promoting the Quality of Medicines Program (PQM) and other activities, serves as a primary mechanism to help USAID-supported countries strengthen their quality assurance (QA) and quality control (QC) systems to better ensure the quality of medicines that reach patients. The four key objectives of the PQM program are to (i) strengthen QA and QC systems, (ii) increase the supply of quality assured medicines, (iii) combat the availability of substandard and counterfeit medicines and, (iv) provide technical leadership and global advocacy.8

Given the importance of identification and removal of SSFFC medical products from the market in order to ensure access to quality essential medicines and medical devices, particularly in the fight against artemisinin resistance in the GMS, and in the light of the Member State Mechanism on SSFFC medical products’ call for expansion of the WHO Global surveillance and monitoring project to all regions, a workshop was held to raise awareness of the need for SSFFC surveillance and information sharing in the WHO South East Asia Region, including two countries of the GMS, among national regulatory authorities and to train country focal persons on the WHO SSFFC global surveillance and monitoring rapid alert system. The workshop was convened under the auspices of the WHO with technical input from the USP. It was supported by the Asian Development Bank under the Regional Malaria and other communicable Diseases Trust Fund with additional support from the United States Agency for International Development Agency (USAID) through USP-PQM and hosted and supported by the Indonesian National Agency of Drug and Food Control (Badan POM).

Objectives
The objectives of the meeting were to:
1. Strengthen regulatory capacity in the region to prevent, detect and respond to SSFFC medical products.
2. Increase awareness within national regulatory authorities of the dangers of SSFFC medical products.
3. Emphasise the importance of post market surveillance and the reporting of SSFFC medical products in order to protect public health.
4. Increase knowledge of laboratory support, field detection technologies and sampling methodologies.
5. Increase awareness of the importance of good distribution practice and supply chain integrity.
6. Train nominated country focal persons from the National Medicines Regulatory Authorities in the use of the WHO global surveillance and monitoring rapid alert system for reporting SSFFC medical products.

Expected Outcomes
The expected outcomes of the training workshop are:

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1. Increased reporting of SSFFC medical products from the region to the WHO Global SSFFC surveillance and monitoring system.
2. Development of a more effective network amongst National Regulatory Authorities in the region with increased information sharing concerning SSFFC medical products.
3. Increased reporting and issuance in regional alerts concerning SSFFC medical products.
4. Greater access and use of the WHO search tools for SSFFC medical products.

Participants and resource persons
Twelve countries were invited to send participants to the training workshop and eleven were able to attend. Indonesia included additional participants and the attendance of participants from 3 states as well as central regulatory agency in India were supported. The programme with details of key resource persons is given in Annex 1 and a list of participants is provided in Annex 2. Key resource persons were:

- **Mr Michael Deats**: Group Lead: SSFFC Surveillance and Monitoring Programme; Safety and Vigilance Unit, Essential Medicines and Health Technologies Department, World Health Organisation.
- **Mrs Pernette Bourdillon Esteve**: Analyst: SSFFC Surveillance and Monitoring Programme; Safety and Vigilance Unit, Essential Medicines and Health Technologies Department, World Health Organisation.
- **Mr Chris Maguire**: Intelligence enforcement officer, Health Products Regulatory Authority, Ireland.
- **Dr Souly Phanouvong**, Senior Manager, Asia Programs, Promoting the Quality of Medicines Program (PQM), United States Pharmacopeial Convention.
- **Dr Yanga Dijiba**, Program Manager, SE Asia - Promoting the Quality of Medicines (PQM), United States Pharmacopeial Convention.
- **Prof Paul Newton**, Reader in Tropical Medicine at the University of Oxford, and Head of Medicine Quality Group of the Worldwide Antimalarial Resistance Network (WWARN).

Training Workshop Proceedings

**Day 1 – Monday 10 October 2016**
The inaugural session started with welcome addresses from the main partners. Dr Ondri Dwi Sampurno of Badan POM welcomed participants to Jakarta and the workshop. His views of the threats and impact of SSFFC medical products were echoed by Dr Jihane Tawilah, Representative of the World Health Organization in Indonesia, Mr Jonathan Ross, USAID Indonesia office and Dr Rooswanti Soeharno of the Asian Development Bank Resident Mission in Indonesia, each of whom greeted participants and wished for a successful workshop.

![Fig. 1: Honourable Guests in the Opening Ceremony: Badan POM, USAID. WHO and ADB representatives](image-url)
Mr Michael Deats, Group Lead of the SSFFC Surveillance and Monitoring Programme at the World Health Organization (WHO) welcomed participants, and thanked partners for their support. He outlined the importance of SSFFC surveillance and introduced to the workshop agenda. He gave an overview of the global SSFFC medical products situation including developments in the definitions of ‘substandard’, ‘falsified’ and ‘unregistered’ medical products. The value of the WHO SSFFC surveillance scheme was underlined and how it could support a rapid response by NRAs to threats posed by SSFFC products identified on the market wherever they might first appear internationally. Participants were introduced to the online portal for reporting suspected SSFFC medical products to WHO and the database of reports currently available.

Day 2 – Tuesday 11 October 2016

The morning involved an interactive session discussing the identification of a suspected SSFFC, how to manage, investigate and report an SSFFC incident. The importance of good documentation and sound procedures was underlined. This was followed by an overview of the necessary laboratory support for SSFFC identification and investigation by USP. The requirements for national laboratory ISO-17025 accreditation were discussed as well as the use of field detection equipment to aid in screening and identification of SSFFC medical products. A few selected devices were demonstrated to participants. Participants then gained experience in making a report using the online portal by working on a real world example. The final session was led by Paul Newton describing the problem of SSFFC antimalarials in the South-East Asia region, and the Greater Mekong Subregion in particular. This underlined the importance for good regulatory practice and rapid reporting and detection of SSFFC malaria medical products.

Day 3 – Wednesday 12 October 2016

Additional training on the use of the WHO online reporting portal was provided through practical examples. This was followed by a focus on supply chains and post-marketing surveillance, including good distribution practice, sampling strategies, and the collection of appropriately documented evidence. Strategies to combat SSFFC medical products were discussed in an interactive session including those involved in prevention, detection and response. Klara Tisocki, the WHO Regional Advisor on Essential Medicines presented on regional collaborations to enhance the response to SSFFC medical products. The final presentation was by Chris McGuire who provided an introduction to actions that can be taken to investigate and act upon the internet sales of medicines and websites supplying medical products.
The meeting ended with an assessment of knowledge gained during the training followed by presentation of certificates of attendance and votes of thanks.

Discussion
This workshop was well-attended by participants from member states with 55 participants from 11 countries. A joint WHO-USP workshop with the support of ADB and Badan POM made efficient use of partner and NRA resources and allowed for interaction between regulators from various countries as well as between laboratory support personnel. The WHO regional advisor on medicines was able to meet with participants to identify needs they might have in this area and to identify support they would require in the future.

Important issues that were identified from the interactive discussion with participants included:

- Combating SSFFCs requires resources and NRAs face resource constraints and capacity to address them effectively
- NRAs should work together and share information on SSFFCs in a timely manner as well as collaborate effectively with national Customs, police and other enforcement agencies to address SSFFCs e.g. through national taskforces
- The WHO SSFFC online reporting portal and database are useful tools to help NRAs share and investigate incidents
- A smartphone application is being tested to support the reporting of suspected SSFFCs to the NRAs
- Internet sale of illegal and SSFFCs has become an increasing concern in the region and need to be regulated and addressed.

Workshop evaluation and knowledge check

The training workshop objectives were met in that awareness and knowledge of SSFFC medical products and means to prevent, detect and respond to them was increased among regulators in the region. NRA focal points for reporting to the WHO surveillance and monitoring system were identified and trained and participants were made aware of laboratory and field detection technologies to support activities against SSFFC products.

A summary of the workshop evaluation and pre/post-workshop knowledge tests is provided in Annex 3. The comments indicated that more examples and experiences from low-resourced countries would be welcomed with information on how to identify and address SSFFC products on the market and how to develop communication messages and strategies to inform stakeholders. Workshop evaluation showed that most participants were satisfied with the workshop organisation and training. Self-assessment of skills gained identified that the proportion of those reporting good or high skills increased by between 47% and 73% on all measures (Annex 3). A questionnaire of desires for regulatory collaboration elicited a variety of responses from the countries (Annex 4; Annex 5).

Assessment of outcomes will require analysis of reporting to the WHO surveillance and monitoring system from the region and use of the tools on the portal website over time. The challenge of having high-level support from within the respective NRAs to implement and provide operational support for the focal persons to perform their function will be critical to achieve the outcomes.
Photo Gallery of Country Representatives
## Annex 1 - Programme agenda

### DAY 1 | MONDAY, 10TH OCTOBER

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
<th>Presenter/Institution</th>
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<tbody>
<tr>
<td>08.30-09.00</td>
<td>Registration</td>
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<tr>
<td>09.00-10.00</td>
<td>Welcome and Formal Opening</td>
<td>Dr Ir Penny K Lukito, <em>Indonesia National Agency of Drug and Food Control</em></td>
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<tr>
<td></td>
<td></td>
<td>Dr J. F. Tawilah, <em>World Health Organization</em></td>
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<tr>
<td></td>
<td></td>
<td>Dr Jonathan Ross, <em>Director, Office of Health, USAID Indonesia, USP-PQM</em></td>
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<tr>
<td></td>
<td></td>
<td>Dr Rooswanti Soeharno, <em>Indonesia Resident Mission, Asian Development Bank</em></td>
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</tbody>
</table>
| 10.00-10.30 | Introductions, Administration and Agenda | - Introduction of participants and facilitators  
- Structure of the workshop and expected outcomes |
|           |                                | Douglas Ball, *Asian Development Bank*                                                 |
|           |                                | Michael Deats, *World Health Organization*                                             |
| 10.30-11.00 | Refreshments Break and Official Photograph |                                                                                       |
| 11.00-12.00 | Knowledge Check               | Souly Phanouvong, *USP-PQM*                                                            |
| 12.00-13.00 | Lunch                         | All delegates                                                                         |
| 13.00-14.00 | WHO Global Overview           | World Health Organization                                                               |
| 14.00-15.00 | Group Exercise 1: Establishing the facts | - Scope                               
- Scale                                
- Harm                                 |
|           |                                | World Health Organization                                                               |
|           |                                | All delegates                                                                         |
| 15.00-15.30 | Introduction to the WHO Surveillance and Monitoring System | - How it works                          |
|           |                                | World Health Organization                                                               |
| 15.30-16.00 | Refreshment Break             |                                                                                       |
| 16.00-17.00 | Using the Portal             | World Health Organization                                                               |
|           |                                | - Reporting and searching the database                                                |
|           |                                | - The role of the focal point                                                          |
## DAY 2 | TUESDAY, 11TH OCTOBER

### Exercise 2. Managing an incident – Case Study
- Initial steps
- Risk Assessment
- Protecting public health
- Verification
- Investigation

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<tr>
<th>Time</th>
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<tr>
<td>09.00-10.30</td>
<td>Exercise 2. Managing an incident – Case Study</td>
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World Health Organization
All delegates

### Refreshment Break

<table>
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<th>Time</th>
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<tbody>
<tr>
<td>10.30-11.00</td>
<td>Refreshment Break</td>
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### Laboratory Support and Capacity
- Regional Focus
- Methodology
- Interpreting results

<table>
<thead>
<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>11.00-12.00</td>
<td>Laboratory Support and Capacity</td>
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Dr Souly Phanouvong, USP-PQM
World Health Organization

### Lunch

<table>
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<th>Time</th>
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<tbody>
<tr>
<td>12.00-13.00</td>
<td>Lunch</td>
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### Field Testing Equipment
- Demonstration and applications
- Methodologies

<table>
<thead>
<tr>
<th>Time</th>
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<tbody>
<tr>
<td>13.00-14.00</td>
<td>Field Testing Equipment</td>
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Dr Yanga Dijiba, USP-PQM

### Refreshment Break

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<th>Time</th>
<th>Session</th>
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<tr>
<td>15.30-16.00</td>
<td>Refreshment Break</td>
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### Exercise 3. Using the WHO Portal
- Hepatitis C - Case Study
- Reporting to WHO

<table>
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<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>14.00-15.30</td>
<td>Exercise 3. Using the WHO Portal</td>
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World Health Organization
All delegates

### Social Event

<table>
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<tr>
<th>Time</th>
<th>Session</th>
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<tbody>
<tr>
<td>19.00-21.00</td>
<td>Social Event</td>
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<tr>
<td>Time</td>
<td>Session</td>
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</tr>
<tr>
<td>09.00-10.30</td>
<td><strong>Exercise 4: Using the Portal</strong>&lt;br&gt;▪ Vaccines Case Study</td>
</tr>
<tr>
<td>10.30-11.00</td>
<td>Refreshment Break</td>
</tr>
<tr>
<td>11.00-12.00</td>
<td><strong>Post Marketing Surveillance</strong>&lt;br&gt;▪ Sampling strategies&lt;br&gt;▪ Photographs&lt;br&gt;▪ Record Keeping&lt;br&gt;▪ Laboratory testing</td>
</tr>
<tr>
<td>12.00-13.00</td>
<td>Lunch</td>
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<tr>
<td>13.00-14.00</td>
<td><strong>Good Distribution Practice</strong>&lt;br&gt;▪ Practice and procedures</td>
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<tr>
<td>14.00-14.45</td>
<td><strong>Strategies to combat SSFFC medical products</strong>&lt;br&gt;▪ Prevention&lt;br&gt;▪ Detection&lt;br&gt;▪ Response</td>
</tr>
<tr>
<td>14.45-15.00</td>
<td><strong>SEARO regulatory network</strong></td>
</tr>
<tr>
<td>15.00-15.30</td>
<td><strong>Websites supplying Medical products</strong>&lt;br&gt;▪ Public use of on line pharmacies&lt;br&gt;▪ High profits, low risk&lt;br&gt;▪ Targeting fake online pharmacies effectively&lt;br&gt;▪ International law for tackling on line pharmacies</td>
</tr>
<tr>
<td>15.30-16.00</td>
<td>Refreshment break</td>
</tr>
<tr>
<td>16.00-17.00</td>
<td><strong>Conclusion</strong>&lt;br&gt;▪ Knowledge Check&lt;br&gt;▪ Certificates&lt;br&gt;▪ Photographs</td>
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</table>
### Annex 2: List of participants

<table>
<thead>
<tr>
<th>Country</th>
<th>Name</th>
<th>Title/Position</th>
<th>Organization</th>
<th>Location</th>
<th>Email</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Bangladesh</strong></td>
<td>Mr Mohammad Mozammel Hossain</td>
<td>Assistant Director</td>
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<td></td>
<td>Mr A.T.M. Golam Kibria Khan</td>
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<td>Directorate General of Drug Administration</td>
<td>Dhaka, Bangladesh</td>
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<tr>
<td></td>
<td>Dr Nasima Pervin</td>
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<tr>
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<tr>
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<td></td>
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<tr>
<td><strong>India</strong></td>
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<tr>
<td></td>
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<td>Mr Lalsawma</td>
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<tr>
<td></td>
<td>Mr Hrushikes Mahapatra</td>
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<tr>
<td></td>
<td>Mr Navneet Marwaha</td>
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<td>Himachal Pradesh</td>
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<tr>
<td></td>
<td>Dr Ajay Sachan</td>
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<td>North Zone, CGO Building I</td>
<td><a href="mailto:cdsconz@gmail.com">cdsconz@gmail.com</a></td>
</tr>
<tr>
<td><strong>Democratic People’s Republic of Korea</strong></td>
<td>Unable to attend</td>
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</table>
Mr Omprakash Shobhraj Sadhwani  
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Annex 3. Workshop evaluation (51 respondents)

**Logistics Satisfaction**

- Hotel
- Registration
- Food
- Training Material

- Disagree strongly
- Disagree
- Neutral
- Agree
- Agree strongly
- NA

**Training Satisfaction**

- Met personal objectives
- Training material
- Practical exercises
- Content & topics
- Impact of training

- Disagree strongly
- Disagree
- Neutral
- Agree
- Agree strongly
- NA
Instructors allowed an appropriate level of participation

Instructor's Presentation and Material
Increase in and total % of respondents reporting good or high skills by the end of the workshop

<table>
<thead>
<tr>
<th>Area</th>
<th>Increase in %</th>
<th>Total %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Using the portal</td>
<td>75%</td>
<td>80%</td>
</tr>
<tr>
<td>Lab support &amp; capacity</td>
<td>50%</td>
<td>55%</td>
</tr>
<tr>
<td>Field testing equipment</td>
<td>40%</td>
<td>45%</td>
</tr>
<tr>
<td>Post marketing surveillance</td>
<td>30%</td>
<td>35%</td>
</tr>
<tr>
<td>Good Distribution Practices</td>
<td>20%</td>
<td>25%</td>
</tr>
<tr>
<td>Strategies to combat SSFFC</td>
<td>10%</td>
<td>15%</td>
</tr>
<tr>
<td>Regional collaboration</td>
<td>5%</td>
<td>10%</td>
</tr>
</tbody>
</table>

- Increase in % of participants rating themselves as having good or high skills after training
- Total % rating themselves with good or high skills after training

Suggestions for Workshop Improvement

- More Practical and Discussion: 27%
- Longer duration: 23%
- Sharing best practices: 8%
- More training topics: 8%
- Others: 18%
- No answer: 16%
- Others: 18%

Increase in % of respondents reporting good or high skills by the end of the workshop.
The Best of the Workshop

- No answer: 9%
- Logistics: 6%
- Using the portal: 17%
- Training topic and material: 18%
- Pricals/Exercises: 12%
- Networking among regions: 11%
- The instructors: 19%
- Interactive discussion: 8%
- Food: 8%
- No prayer room: 10%
- Bad sound system: 10%
- Duration too short: 12%
- Lab topics: 13%
- Insufficient practical: 6%
- Language barrier: 4%
- No answer: 37%

The Worst of the Workshop

- No answer: 37%
- Duration too short: 12%
- Insufficient practical: 6%
- Language barrier: 4%
- Lab topics: 13%
- Food: 8%
- No prayer room: 10%
- Bad sound system: 10%

Using the portal: 17%
Training topic and material: 18%
Practicals/Exercises: 12%
Networking among regions: 11%
The instructors: 19%
Interactive discussion: 8%
No answer: 9%
Logistics: 6%
### Annex 4. Questionnaire on regulatory collaboration on SSFFCs

<table>
<thead>
<tr>
<th>Questions -&gt;</th>
<th>What do you need to improve your collaboration with key stakeholders within your country for more successful prevention, detection and response to SSFFC medical products</th>
<th>What do you need to improve your collaboration with key stakeholders across the region for more successful prevention, detection and response to SSFFC medical products</th>
<th>After this workshop what short term support you would like to get from external partners like WHO, USP, ADB, if you need any, within the next 6 months to support your work?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Countries</td>
<td></td>
<td>Name top three countries/NRA whom you would like to have stronger collaboration in this area?</td>
<td></td>
</tr>
</tbody>
</table>
| **BANGLADESH** | • Collaboration among the government agency like Customs, Law enforcement agency & DGDA should work together, especially in every point of entry like ports. There should be a office of DG, Drugs.  
  • For identification of SSFFC medical product, DGDA need minilab, more training like this one.  
  • Special Team to work against SSFFC medical products. In every training on SSFFC medical product these team member will participate. | 1. India  
  2. Myanmar  
  3. Thailand                                                                 | • We need  
  o Field Testing Equipments  
  o Minilab  
  o HPLC, Raman Spectra photometer, TLC, Pharmachk, C6  
  • More training on SSFFC medical products  
  • GSMS webpage online reporting, in this case many of DGDA officer at district level do not have even internet access. |
| **BHUTAN**    | • Improve collaboration with customs  
  • Conduct regular meeting with customs, police & Ministry of communication & Information  
  • Laboratory support from Drug Testing laboratory, Ministry of Health  
  • Collaborations with customs officials  
  • Collaborations with the | 1. India  
  2. PRC  
  3. Singapore  
  1. Thailand  
  2. Indonesia  
  3. India                                                                 | Getting assistance to track and or give pressure to manufacturers/distributors based outside our territory associated with SSFFC Medical product  
  1. Support from USP and WHO for reference standards and reagents |
<table>
<thead>
<tr>
<th>Procurement agencies and health facilities</th>
<th>Procurement (for mini lab testing of medicines)</th>
<th><strong>Training</strong> on detection and assessment of SSFFC medical products for field inspectors</th>
<th><strong>Support</strong> to procure incinerator for dispose of expired, quality failed and defective products to prevent re-circulation to the market.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>INDIA</strong></td>
<td></td>
<td><strong>Nepal, Sri Lanka, Bangladesh and other SARRC/SEARO countries</strong></td>
<td><strong>Visits of FOCAL POINTS OF SSFFC to expert countries to gain knowledge on SSFFC control.</strong></td>
</tr>
<tr>
<td>• A common digital platform/portal for real time reporting of SSFFCs. The platform should be kept confidential among regulatory authorities with access codified.</td>
<td>• A common digital platform on real time reporting of trans-border SSFFC in SAAIRC/SEARO region.</td>
<td>• Sharing of expertise mutually with respect to detection/prevention/investigation/GMP and GDP/testing &amp; prosecution/evidence sharing against SSFFC products</td>
<td>• Getting involved with WHO/other healthcare agencies/institutions at global level in further understanding and implementing the SSFFC mechanism</td>
</tr>
<tr>
<td>• Adequate infrastructure in terms of man-power and testing facilities with particular emphasis on providing adequate facilities to field staff/inspectorate staff.</td>
<td>• Non-availability of mobile rapid detection technologies/instruments based on non-invasive techniques like scanning of packages like NIR/Raman spectroscopy etc.</td>
<td>• Lack of international exposure on the latest updates on tools to combat SSFFC including cyber expertise</td>
<td>• Mutual co-operation/networking at global level for SSFFC reporting &amp; prevention.</td>
</tr>
<tr>
<td>• Non-availability of mobile rapid detection technologies/instruments based on non-invasive techniques like scanning of packages like NIR/Raman spectroscopy etc.</td>
<td>• Lack of international exposure on the latest updates on tools to combat SSFFC including cyber expertise</td>
<td>• Visits of FOCAL POINTS OF SSFFC to expert countries to gain knowledge on SSFFC control.</td>
<td></td>
</tr>
</tbody>
</table>
| INDONESIA | • Establish engagement with all key stakeholders to combat SSFFC meds  
• Get the same vision  
• Building trust between all the stakeholders  
• We need to increase awareness, competency and commitment of key stakeholder to combating counterfeit medical products  
• Capacity building to improve competency for detection technology and do investigation  
• Integrated system for medical products distribution control  
• Regulations that state/clearly declare the responsibility of each institution/stakeholder based on the authority and competency.  
• The same perception about “SSFFC medical products is threat to public health badly”, so we must handle this matter together.  
• Same prospective among stakeholders regarding the dangerousness of SSFFC medical products  
• Develop investigation lab  
• Exchange officers among LEA  
• Capacity and capability in conducting laboratory test. | 1. UK  
2. Australia  
3. India  
We need to integrate collaboration to prevent detection & response to SSFFC medical product  
Top three countries:  
1. China  
2. India  
3. Singapore  
1. China  
2. India  
3. Singapore  
• Sharing knowledge and data/information  
• Capacity building  
• Collaboration in Post Marketing Surveillance/Investigation  
1. China  
2. India  
3. Singapore  
• Exchange of information  
• Comprehensive trainings on investigating SSFFC medicines  
We would like to get training, workshop or on job training in some countries which have better system than our country for combating SSFFC medical product  
• Sharing regulation that has not been in exist in my country (e.g. Regulation about online pharmacies)  
• Provide information needed for consultation  
• Sustainable internet investigation training throughout Indonesia (all provinces) |
<table>
<thead>
<tr>
<th>Country</th>
<th>Requirements</th>
<th>Countries/Regional Networks</th>
<th>Technical Assistance</th>
</tr>
</thead>
</table>
| MALDIVES  | • Improve communication between the Regulatory Authority and Health care professional, other relevant organization so that they can report on suspected SSFFC. | 1. India  
2. Sri Lanka  
3. Malasia | • We look forward for the establishment of the Regional Network which would be very helpful.  
• Capacity building specially in establishing pharmaceutical testing laboratory. |
| MYANMAR   | 1. Strengthen the FDA department (central as well as state/regional level)  
2. Strengthen national laboratory capacity in quality testing of medicines by promoting PMS  
3. Close collaboration & coordination between FDA and departments under Ministry of Health & support and other allied ministries  
4. Nominate National focal Point to report GSMS (Global surveillance & Monitoring system) for SSFFC  
5. Vitalize adverse Drug Reaction Committee which has already formed | • India, Thailand and Indonesia (especially NRAs)  
• Need technical assistance from SEARO/WHO | 1. Capacity Building  
2. Technical Assistance (Myanmar is in process to reach ISO lab FDA)  
Support of Laboratory equipment’s (Mini Lab in state/regional level FDA) |
| NEPAL | • MoHP co-ordination with DA to control illegal entry of drug in border region  
• Availability of tool for detection in branch office of DDA in different region  
• Custom manpower for conducting SSFFC & reporting DDA  
• Proper method of drug registration from importers, wholesalers, distributors & retailers | 1. Thailand  
2. Indonesia  
3. India | • Capacity building in term of SSFFC in regulatory  
• Program to purchase the tools for detection of SSFFC like, RAMAN, Minilab & training to use tools  
• Program to update pharmacovigilance area in DDA of Nepal which is inactive right now.  
• If DV is active, then SSFFC can be identified  
• Training to DDA inspector & QC personnel on detecting of SSFFC |
| SRI LANKA | • Identification of other stake holders such as postal department, police, customs etc. and develop a collaboration among each other.  
• Educating the stakeholders about the gravity of the problem and make them convincing about importance of reporting the problem to a National Focal Point whenever such an incident is encountered.  
• Develop a guideline to be followed. | 1. India  
2. Singapore  
3. Thailand or Malaysia | • To enhance the capacity to identify SSFFC products at field level to gift field test kits.  
• Support to purchase reference standard to the national lab  
• Periodic review of the training  
• Short term training programme on QS GMP Law enforcement  
• Organizing a review programme to share the progress of participants after a specified period would be useful. |
| THAILAND | Hospitals | 1. Laos PDR  
2. Myanmar  
3. Singapore | Risk Assessment |
| TIMOR LESTE | • Establish and implement a system of cooperation among countries in the region  
  • Increase access to the accuracy of the information regarding wifi SSFFC alert and sharing the data. | 1. Indonesia  
  2. Thailand  
  3. India | • Training capacity building to strengthening regulator and laboratories  
  • Technical support to establish standard operational procedures of the SSFFC in national level. |

| PAPUA NEW GUINEA | • Strengthen collaboration with review of existing MOA/MOU with other government regulatory and enforcement agencies  
  • Customs  
  • Police | 1. India  
  2. Indonesia  
  2. Capacity building on detection techniques for the national inspectors and Customs officer.  
  3. Capacity building Licensing procedures for manufacturers, wholesalers, distributors, Importers, Exporters |
Annex 5. Depiction of regulatory collaboration wishes based on questionnaire