Addressing the Barriers to Effective Monitoring, Reporting and Containment of Spurious/Substandard/Falsely-labelled/Falsified/Counterfeit Medical Products through Sustainable Multi-stakeholder Collaboration and Community/Consumer-based Interventions

A report prepared for the Medicines Transparency Alliance, Philippines

Yolanda R. Robles, RPh, PhD
Jean Flor C. Casauay, RPh, MS
Bryan Paul I. Bulatao, RPh, MS
# Table of Contents

LIST OF TABLES ......................................................................................................................... 3  
LIST OF FIGURES ......................................................................................................................... 4  
GLOSSARY OF ACRONYMS .......................................................................................................... 5  

I. BACKGROUND .......................................................................................................................... 7  
   A. The Global Problem of Counterfeit Medicines ............................................................................. 8  
   B. Gaps in the Pharmaceutical Supply Chain ................................................................................. 9  
   C. Public Health and Trade Consequences of SSFFC Medicinal Products ..................................... 12  

II. RATIONALE / SIGNIFICANCE OF THE STUDY ................................................................... 14  

IV. METHODOLOGY ..................................................................................................................... 16  

V. RESULTS ................................................................................................................................... 17  
   A. Multi-stakeholder Collaboration ................................................................................................. 17  
   B. Situational Analysis of SSFFC Monitoring, Reporting, and Containment in the Philippines .......................................................... 30  
   C. Strengths, Weaknesses, and Areas for Improvement of the National Regulatory Framework ........................................................................................................... 39  
   D. Proposed Models of Multi-Stakeholders Collaboration ............................................................. 50  
      1. Model 1: The SSFFC Council........................................................................................................ 53  
      2. Model 2: The FDA SSFFC Task Force......................................................................................... 57  
      3. Model 3: The Coalition for Safe Medicines (Modified)............................................................... 60  

VI. CONCLUSION .......................................................................................................................... 62  

VII. REFERENCES .......................................................................................................................... 63  

VIII. APPENDICES ......................................................................................................................... 66  
   A. APPENDIX A: Letter of Request for KII ................................................................................. 67  
   B. APPENDIX B: Interview Schedule for Government Agencies .................................................. 68  
   C. APPENDIX C: Interview Schedule for Non-Government Organizations .................................... 69  
   D. APPENDIX D: Health Policy Note 1 .......................................................................................... 70  
   E. APPENDIX E: Health Policy Note 2 .......................................................................................... 74  
   F. APPENDIX F: Health Policy Note 3 .......................................................................................... 81
LIST OF TABLES

Table 1. Identified Stakeholders for the Study................................................................................. 16
Table 2. US Regulations to Control Counterfeiting.......................................................................... 18
Table 3. Duties of Government Agencies Involved in the Crackdown on Counterfeit Medicines.................................................................................................................. 27
Table 4. Institutions which Participated in the Key Informant Interviews.................................... 30
Table 5. Identified Barrier by Different Government Agencies......................................................... 33
Table 6. Perceived Weaknesses and Barriers by Non-government Stakeholder............................ 35
Table 7. Monitoring Procedure for Counterfeit Drugs in the Market.............................................. 42
Table 8. Procedure for Filing Administrative Complaint Depending on the Complainant.............. 44
Table 9. Proposed Phases of Implementation for Model 1............................................................... 56
Table 10. Proposed Phases of Implementation for Model 2............................................................ 59
Table 11. Proposed Phases of Implementation for Model 3............................................................. 62
LIST OF FIGURES

Figure 1. The Pharmaceutical Supply Chain
Figure 2. The US Counterfeit Alert Network Model
Figure 3. FDA and Its Leadership Position in Multi-stakeholder Collaboration
Figure 4. The Nigerian Task Force on Counterfeit and Fake Medicines
Figure 5. Indonesia’s Mechanism of National Coordination
Figure 6. Framework of the Cross-Departmental Task Force on Counterfeit Medicines in Taiwan
Figure 7. Information Flow in the Proactive/Reactive Communication Strategy Using a Multi-stakeholder Approach
Figure 8. Summary of weaknesses and barriers from government and non-government stakeholders
Figure 9. The Organizational Structure of the Coalition for Safe Medicines
Figure 10. The Structure-Process-Outcomes Method of Analysis
Figure 11. Regulatory Framework for the Pharmaceutical Sector
Figure 12. IMPACT’s Five Key Areas
Figure 13. Attributes of Typical Stakeholders in a Collaborative Partnership
Figure 14. The SSFFC Council
Figure 15. The National SSFFC Task Force Model
Figure 16. The Modified Organizational Structure of the Coalition for Safe Medicines
GLOSSARY OF ACRONYMS

ACCU – Anti-Cybercrime Unit
AFCCU – Anti-Fraud Commercial Crimes Unit
AHSP – American Society of Health-System Pharmacists
API – Active Pharmaceutical Ingredient
BOC – Bureau of Customs
BAC – Bids and Awards Committee
BFAD – Bureau of Food and Drugs
CAN – Counterfeit Alert Network
CAPA – Center for Asia Pacific Aviation
CDRR – Center for Drug Regulation and Research
CIDG – Criminal Investigation and Detection Group
CHD – Centers for Health Development
DOH – Department of Health
DSAP – Drugstores Association of the Philippines
DHSSPS – United Kingdom Department of Health, Social Services, and Public Safety
DPIO – District Police Intelligence Office
DRA – Drug Regulation Authority
EDQM – European Directorate for the Quality of Medicines and Healthcare
EU – European Union
FDA – Food and Drug Administration
FDRO – Food and Drug Regulatory Office
GMP – Good Manufacturing Practice
HDMA – Healthcare Distribution Management Association
IEC – Information, Education, Communication
IMPACT – International Medical Products Anti-Counterfeiting Task Force
IPO – Intellectual Property Officer
IPR – Intellectual Property Rights
IRPMA – International Research-based Pharmaceutical Manufacturers Association
IRR – Implementing Rules and Regulations
KII – Key Informant Interview
LGU – Local Government Unit
LICD – Legal, Information and Compliance Division
LSD – Laboratory Services Division
MHRA – Medicines and Healthcare Products Regulatory Agency
MoH – Ministry of Health
MRA – Medicine Regulatory Authority
NABP – National Association of Boards of Pharmacy
NACDS – National Association of Chain Drug Stores
NADFC – National Agency for Drug and Food Control
NAFDAC – National Agency of Food and Drug Administration and Control
NBI – National Bureau of Investigation
PDEA – Philippine Drug Enforcement Agency
PhRMA – Pharmaceutical Research and Manufacturers of America
PMA – Philippine Medical Association
PNG – Papua New Guinea
PPhA – Philippine Pharmacists Association
PSD – Product Services Division
PSTF – Preventative Services Task Force
RA - Republic Act
REU – Regional Extension Unit
RFID – Radio-Frequency Identification
SSFFC – Substandard, Spurious, Falsely-labelled, Falsified, Counterfeit
SPOC – Single Point of Contact
TMPACT – Taiwan Medical Products Anti-Counterfeiting Task Force
TPMDA – Taiwan Pharmaceutical Manufacturers and Distributors Association
TPMMA – Taiwan Pharmaceutical Marketing and Management Association
UK – United Kingdom
UNICRI – United Nations Interregional Crime and Justice Institute
US – United States
USPCCI – United States Pharmacopeial Convention, Inc
VIPPS – Verified Internet Pharmacy Practices Sites
WHO – World Health Organization
I. BACKGROUND

Medicines are made available in all health care systems to address the health problems of the population. It is expected that they conform to national and international standards of quality, efficacy and safety. These attributes have to be maintained at all points of the pharmaceutical supply chain up to the point of care to achieve positive health outcomes. When Spurious/Substandard/Falsely-labelled/Falsified/Counterfeit (SSFFC) pharmaceutical products enter the commercial market, they brought in health, political and economic burden. While the proliferation of SSFFC is a known complex and global issue that transcends national boundaries, it is expected that governments have the capacity to provide technical and regulatory measures to control the entry and distribution of these questionable medicinal products.

The World Health Organization (WHO) defines “Substandard/Spurious/Falsely-labelled/Falsified/Counterfeit (SSFFC) medical products” as medical products that are outside of specifications, which includes intentional, reckless or negligent errors, false packaging, and those intended to deliberately deceive and imitate a genuine product (WHO, n.d.). This definition was further broadened in the Philippine definition of Counterfeit Drugs which included unregistered products with the Philippine Food and Drug Administration, regardless of conformity to quality specifications. The Philippine Republic Act No. 8203, otherwise known as the “Special Law on Counterfeit Drugs,” refers to a counterfeit product as a medicine with correct ingredients in wrong amounts, wrong ingredients, without active ingredients, or with sufficient quantity of active ingredient that results in the reduction of the drug's safety, efficacy, quality, strength or purity. It may be deliberately and fraudulently mislabeled with respect to identity and source or with fake packaging, and can be applied to both branded and generic products (Special Law on Counterfeit Drugs, 1996). Furthermore, it may also be referred to as: (1) the drug itself or the container or labeling which bears a trademark, tradename or other identification mark or imprint of a Bureau of Patent, Trademark and Technology Transfer-registered natural or juridical person; (2) a drug product refilled by unauthorized persons if the legitimate labels or marks are used; (3) an unregistered drug product except those brought in the country for personal use as confirmed and justified by accompanying medical records; and (4) a drug which contains no amount of or a different active ingredient or less than 80% of the active ingredient it purports to possess as distinguished from an adulterated drug (Special Law on Counterfeit Drugs, 1996, s. 3b). In RA 8203, unregistered products as well as those products which were maliciously produced by unscrupulous entities to deceive and for the purpose of financial gain are in the same category. The application of this law took a different turn when the Supreme Court ruled regarding the case, Roma Drug versus GlaxoSmithKline (GSK) where it
was alleged that Roma Drug had violated RA 8203 for not registering GSK products which were procured under parallel importation. The Supreme Court took the position that the drugstore had not violated the RA 8203. To quote,

“The court stated that Republic Act No. 9502 clearly reveals an intention of the legislature to abrogate the SLCD because of irreconcilable inconsistencies between the two. It ruled that Republic Act No. 9502 nullifies the reason or purpose of the SLCD so the latter loses all meaning and function. Thus, the Supreme Court considered the prosecution of Roma Drug to be no longer warranted. (Sapalo, Velez, Bundang, and Bullian Law Offices, 2014).

Said ruling affected the interpretation and application of the law by FDA. The Philippine definition of counterfeit drugs under RA 8203 has been challenged and as a result, FDA no longer invokes RA 8203 but rather applies the rule of RA 3720 and RA 9711 to cases of unregistered pharmaceutical products, including those obtained through parallel importation.

While there is an obvious difference in the WHO and the Philippine definitions of what counterfeit and SSFFC products are, this study will not dwell on the difference but on the shared attributes of these terms. The barriers that negatively impact on the effective monitoring, reporting and containment of these products appear to be similar regardless of which definition is used. Hence, counterfeit medicines and SSFFC will be used interchangeably in the study.

A. The Global Problem of Counterfeit Medicines

In Africa, parts of Asia, and Latin America, the volume of counterfeit medicines ranges from 10% to 30% of the national legitimate markets while the production and distribution of these medicines in more developed countries is less due to multiple limiting factors such as enhanced legislation, stronger institutions and a more efficient regulatory control. Worldwide estimations of the spread of counterfeit medicines account to 10% of the entire amount of medicines worldwide, and in the United States of America (USA) alone, an increase of 92% in counterfeit drug sales was reported from 2005 to 2010 amounting to $75 billion (UNICRI, 2012).

Counterfeit medicines were not viewed previously as a threat. This is due to a lack of concern and awareness among the population, the uniqueness of ethical drugs, and the fear of companies to lose reputation. However, the changes in social values and technology, combined with globalization, redirect more attention to the control of counterfeit medicines.
B. Gaps in the Pharmaceutical Supply Chain

One way that counterfeit drugs enter the supply chain is through the gaps in the pharmaceutical supply chain. Figure 1 shows the basic components of the pharmaceutical supply chain. The first stage in the supply chain is the sourcing of raw materials, both the active pharmaceutical ingredients (APIs) and the excipients. Almost all generic companies and some research and development-based multinational companies are dependent on API-producing countries like Italy, China, and India or from other companies for their production needs. Pure API companies are not stakeholders in the pharmaceutical sector, *per se* but in developed countries, these companies communicate with the regulatory agency to obtain the Drug Master File, a document used to establish the authenticity of the API. The separation of the API industry from the pharmaceutical industry that put their labels on drug packages creates a potential for quality problems particularly for small manufacturers who have limited resources to verify quality of their APIs at the source level. Poor packaging and use of insufficiently controlled excipients could be additional sources of quality problems (Seiter, 2010).

![Diagram of the Pharmaceutical Supply Chain](image)

*Figure 1. The Pharmaceutical Supply Chain*

Raw materials are manufactured and transported from country to country and involved continuous change of hands of different stakeholders upon crossing provincial or country borders. Repackaging process happens throughout the distribution and shipment procedures and packaging features may be altered (UNICRI, 2012). Even quality raw materials and finished products are transferred to various distributors - major wholesalers, government agencies, and
secondary wholesalers; secondary wholesalers were the primary means by which counterfeit products enter the drug distribution chain through arbitrage (deKieffer, 2006). *Arbitrage* has been defined as, "the simultaneous purchase and sale of an asset on order to profit from a difference in the price. It is a trade that profits by exploiting price differences of identical or similar financial instruments on different markets or in different forms" (Investopedia, 2015).

For example, in the European Union (EU), parallel trade led to entry of counterfeit drugs in the European market. Medicines in Greece imported for the use of its citizens are re-exported to other European countries where they command higher prices and therefore, larger profit for the traders. As quoted, "The trade is an arbitrage between patent medicine prices in different countries which are negotiated between governments and the pharmaceutical industry. Prices are generally set lower in, for example, Greece, Spain and France than in the UK, Germany and Holland. Traders buy 'low' in these countries, transport the products, repackage them in the language of the importing state, and sell them there at a higher price" (Morgan, 2008).

At first, there was no direct evidence linking parallel trade with counterfeit medicines. However, the United Kingdom made several recalls of counterfeit medicines that had entered the UK supply chain through parallel trader. The recalls involved branded products of research-based multinational companies. Some 40,000 tablets were recalled by Medicines and Healthcare products Regulatory Agency (MHRA) and additional 10,000 were further recalled. To trace how the counterfeit medicines enter the supply chain through parallel trade, the following quote is supplied:

"The fakes, packaged in French, were made in China and shipped to Singapore. They were bought by a wholesaler in Luxembourg who sold them on to a Belgian wholesaler and another based in Liverpool, who in turn sold them to UK parallel importers. One of these, OPD, noticed mistakes on the packaging when it was preparing to rebox Zyprexa in English and reported back to Lilly, which informed the MHRA." (Morgan, 2008)

In many countries, procurement of medicines are carried out by different entities – national government, government and non-government health facilities, retail outlets and other trade establishments using different methods and standards. The US Pharmacopeial Convention (2007) has an extensive checklist of the components of an effective procurement system. It stands out that effective procurement have, among others, the following basic characteristics:

- Procurement unit with clear scope of work;
- Well-established regulation and standards including criteria for accrediting suppliers and tracking performance of both suppliers and products; and
• Transparent and well-documented process. (USPCI, 2007)

The choice of supplier is critical to ensuring that available medicines can deliver expected outcomes. A recent example is that of a $38 million medical aid project to Papua New Guinea (PNG) by the Australian government which is expected to deliver much needed essential medicines to the poorest villages of PNG. The project was awarded by the government to a company which was known to be the largest provider of drugs from a notorious Chinese drug company which was a known offender in China’s fake drug crisis. It was reported that the PNG’s Secretary of Health had waived the required quality standards accreditation needed to compete with the tender (Sydney Morning Herald, 2013).

Limited supply of high demand, expensive medicines drive purchasers such as hospitals and other health institutions to seek for alternate sources of these medicines. Counterfeit medicines of branded products like antibiotics enter the supply chain in this manner.

Medicines through the non-traditional distribution channels such as the clinics and the internet have the higher risk of being infiltrated with SSFFC products. More than 50% of the medications purchased online from websites that did not declare their physical addresses were found to be counterfeit (PhRMA, 2011). A survey on internet pharmacies made by the National Association of Boards of Pharmacy (NABP) in the US found that 9938 out of 10,000 of these retailers did not comply with NABP patient safety and pharmacy practice standards or the US State and Federal laws. These retailers declared that they were operating from Canada but are actually a front for offshore illegal operations. The United States and the United Kingdom had set up validation system to secure internet pharmacies where patients can buy their medicines (Sanofi-Aventis, n.d.). However, verification of the legitimacy of internet medicine suppliers has not been adopted yet by many countries.

The supply of medicines is usually under the care and responsibility of the pharmacist in many health care settings. As a health professional educated about medicines from their discovery, development, quality control, production, distribution and use in patients, pharmacists are familiar with the quality characteristics of medicinal products and are supposed to make available only those products with known efficacy, quality and safety. In retail practice, however, when profit orientation and deviation from standard of pharmacy practice override professionalism, it opens the gate for SSFFC products sold through pharmacies. In addition to internet or online pharmacies, legitimate pharmacies may also fall prey to suppliers offering attractive discounts, freebies, and profit margins. It is expected that pharmacies have
procedures for checking authenticity of documents and products from their suppliers. The laxity exercised by some outlets in implementing such procedure made them sell medicines of questionable quality and safety.

Health professionals other than the pharmacist could easily observe physical integrity of drug products but are not trained to detect other quality characteristics of medicines they prescribe or administer. Clinics which engage in the sale of medicines for their patients are also targets for suppliers’ offer of cheap products, some of which were reported to be counterfeits. An online Canadian pharmacy sold $78 Million worth of unapproved, mislabeled, and in two cases counterfeit anti-cancer drugs to doctors across the United States over a period of three years. The company together with its affiliates in the UK and Barbados had become channel for counterfeit medicines (Associated Press, 2015). Patients report medicines of questionable efficacy or their adverse effects only when they have taken the medication and so an alarm is raised among health professionals. Patients are equally unaware of the quality of the medicines they take and are often victims to the danger posed by SSFFC products.

C. Public Health and Trade Consequences of SSFFC Medicinal Products

The public health impact of poor quality medicines cannot be undermined. Since these medicines do not conform to quality standards, then it is expected that they will fail to deliver the expected therapeutic outcomes. Through the years, there was substantial evidence that these medicines endangered lives of patients:

- In Southeast Asia, 38-53% of fake artesunate was obtained from pharmacy and had been sold to patients with malaria. As such, antimicrobial resistance as well as failure of treatment had resulted;
- Hundreds of patients with leishmaniasis failed to respond to miltefosine capsules in Bangladesh;
- Counterfeit insecticide-treated bed nets and vaccines for Neisseria, influenza and rabies did not deliver expected effect thus, prevention of these diseases was aborted;
- Substandard products like primaquine tablets, with 46% of the labeled active ingredient, had caused the development of drug-resistant malaria in Venezuela;
- Some drug products contain active ingredient/s higher than what was written on the label. For narrow therapeutic drugs, this would mean exposing patients to toxic effects of the drugs; and
- A recent survey of seven African countries revealed that many antimalarial drugs as well as sulphadixine/pyrimethamine are substandard and failed dissolution testing.
resulting in poor oral bioavailability and reduced efficacy range of 23-38% and 90%, respectively (Newton, et al. 2010).

Some counterfeit drugs contain harmful ingredients which are potentially fatal. Five hundred children died after ingesting paracetamol containing a renal toxin. In 1995, 89 patients died in Haiti after ingesting cough syrup manufactured with diethylene glycol instead of glycerin. This one is a case of mislabeling, transported to several countries before reaching Haiti. (Newton, et al. 2010; Sanofi-Aventis, n.d.).

At the government level, the occurrence of the above incidents not only affect the health of the people but also reflects failure of health programs with additional economic burden most felt in countries with limited resources.

Commodities like drugs are governed by trade and technical regulations. However, with the entry and distribution of SSFFC in the market, they compete with legitimate suppliers of quality products thus depriving the latter of possible income. Also, the perceived public integrity of a legitimate company may suffer since their product might be tied up with the effect of a counterfeited product. Presently, dubious suppliers were able to cater to retailers and non-traditional outlets that are lenient with their supplier requirements and who lack awareness on counterfeit medicines. These suppliers also ride on existing corrupt practices among public and private procurement bodies. They do not comply with regulatory requirements such as payment of license fees, taxes, business permits, quality tests, submission of technical documents, among others. In so doing, the government is deprived of its income in the form of fees and taxes, and also incurs loss of public funds by buying medicines of poor quality.

SSFFC drug products have the following impact on health and health care systems as summarized by Newton, et al. (2010): (1) increased morbidity and mortality, engendering of drug resistance and loss of medicine efficacy, (2) loss of confidence in health systems and health workers, (3) economic loss for patients, their families, health systems, and the producers and traders of good quality medicines, (4) adverse effects from incorrect active ingredients, (5) waste of enormous human effort and financial outlay in development of medicines, optimizing dosage, clinical trials, policy change discussion, and manufacturing, and (6) increased burden for health workers, medicine regulatory authorities (MRAs), customs officials and police enforcers.
II. RATIONALE / SIGNIFICANCE OF THE STUDY

It is quite clear that the global problem of SSFFC medicinal products is also a grave concern in the Philippines. When available medicines do not conform to national and international standards of quality, efficacy and safety, they can potentially harm those who need medicines for their medical conditions and create additional health risks. Their continuous presence and accessibility also affect the legitimate pharmaceutical industry and robs the government in terms of uncollected fees and wasted expenditure on poor quality medicines. Policy and regulatory measures and their regular implementation are expected to control the entry and distribution of these questionable medicinal products.

In the Philippines, in addition to regulatory requirements for manufacturers and producers of pharmaceutical products, there is a law which provides public protection from counterfeit medicines, RA8203 (Special Law on Counterfeit Drugs). The law defines counterfeit medicines, and describes prohibited acts, the liable parties, the monitoring process, the administrative proceedings and the sanctions and penalties involved. The law also provides for coordination with law enforcement agencies. The lead implementing agency of this law is the Food and Drug Administration (FDA) of the Department of Health. In spite of this policy, counterfeit drugs still proliferate in the country as evidenced by recent reports.

In 2014, two million pesos worth of fake drugs was seized in Baguio City by the Philippine Drug Enforcement Agency (PDEA) and the FDA. The shipment was consisted of an assortment of prescription drugs such as sedatives and opioid analgesics. The fake medicines were believed to be transported from another source in Central Luzon. On December 2013, fake rabies vaccines were reported and confiscated in the Kalinga area in the north of Luzon. Sources of these medicines, according to FDA, may be clinics, drugstores and online stores.

The Philippines, being an archipelago, is vulnerable to illegal entry of smuggled goods, including medicines, from the North to the South of the country. Effective control of entry of SSFFC medicinal products could only happen when borders are guarded, regulations are implemented by the designated agencies, and barriers to monitoring, reporting and containment are addressed through sustainable and collaborative efforts by various stakeholders and the community in general.

The current study aimed to:

- describe the current state of counterfeit drug regulation in the country; and
• propose regulatory models involving several organizations, parties, agencies, and others groups with advocacy on quality and safety of medicines, that will address the issue of SSFFC medical products.

In the long term, this study aims to assist in creating an enforceable counterfeit drug regulatory framework, and in developing amended and new policies in counterfeit drug regulation in the country.

III. OBJECTIVES

• To develop models for sustainable multi-stakeholder collaboration including community/consumer-based interventions to address the identified barriers in the effective monitoring, reporting, and containment of spurious, substandard, falsely-labeled, falsified, or counterfeit (SSFFC) medical products in the Philippines

Specifically, the project aimed to:

• Gather and present examples and cases of effective and sustainable multi-stakeholder collaboration including community/consumer-based interventions in other countries to combat the spread of SSFFC medicinal products;

• Describe the current situation of SSFFC medical products in this country and identify barriers that affect monitoring, reporting, and containment of these products;

• Propose models focusing on multi-stakeholder collaboration and community/consumer-based interventions appropriate to the Philippine setting; and

• Identify needs, resources, and other requirements to support sustainable implementation of proposed models.
IV. METHODOLOGY

To achieve the objectives stated above, the research team utilized the following research methods: The team reviewed the existing literature regarding policies on, and implemented models of counterfeit drug regulation. The team also gathered samples or case studies of existing policies and models of counterfeit drug regulation at the national and international levels. Key informant interviews were conducted and involved experts and/or decision makers involved in counterfeit drug regulation and anti-counterfeit activities in the Philippines. Since there is no group which assumes sustained collaboration with various stakeholders at the moment, the research team had chosen the key informants based on the identified stakeholders in other countries’ models of collaboration. As such, the key informants identified for this study are the following government and non-government entities (Table 1). In this study, matrix that details elements of each model was developed. The agency capabilities, roles, and responsibilities relative to counterfeit drug regulation were analyzed. Lastly, the findings were collated and incorporated in the development of suitable models and their respective policy and implementation frameworks.

Table 1. Identified Stakeholders for the Study

<table>
<thead>
<tr>
<th>GOVERNMENT AGENCIES</th>
<th>NON-GOVERNMENT AGENCIES</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Regulatory Agency:</strong></td>
<td>Local Pharmaceutical Companies</td>
</tr>
<tr>
<td>Food and Drug Administration (FDA)</td>
<td>Multinational Pharmaceutical Companies</td>
</tr>
<tr>
<td>Philippine Drug Enforcement Agency (PDEA)</td>
<td>Drugstores Association of the Philippines (DSAP)</td>
</tr>
<tr>
<td><strong>Enforcement Agencies:</strong></td>
<td>Small Distributors</td>
</tr>
<tr>
<td>Philippine National Police</td>
<td>Large Distributors</td>
</tr>
<tr>
<td>• Criminal Investigation and Detection Group (CIDG)</td>
<td><strong>Professional Organizations:</strong></td>
</tr>
<tr>
<td>• District Police Intelligence Office (DPIO)</td>
<td>Philippine Medical Association (PMA)</td>
</tr>
<tr>
<td>• Anti-Cybercrime Unit (ACU)</td>
<td>Philippine Pharmaceutical Association (PPhA)</td>
</tr>
<tr>
<td>• Anti-Fraud Commercial Crimes Unit (AFCCU)</td>
<td></td>
</tr>
<tr>
<td>National Bureau of Investigations</td>
<td></td>
</tr>
<tr>
<td>Bureau of Customs</td>
<td></td>
</tr>
<tr>
<td>City Health Offices</td>
<td></td>
</tr>
<tr>
<td>Intellectual Property Office</td>
<td></td>
</tr>
</tbody>
</table>
V. RESULTS

A. Multi-stakeholder Collaboration

The multi-stakeholder collaborative approach has been explored in various aspects of public policy and management. It brings together government and non-government entities together in collective meetings to engage in consensus-based decision-making (Ansell and Gash, 2008). To some extent, it is a response to the limitations and failures of the administrative approach to complex policy issues that require identification of various internal and external factors, involvement of key actors outside of the state, and cooperation from the people directly affected by government decisions and resulting policy implementation.

There were cited benefits of collaboration. First is that it can improve the outcomes of the decision-making process by increasing the availability of information available to decision makers, allowing access to diverse knowledge, expertise and ideas. Second is that by having differing opinions, it can unfold a range of uncertainties and risks before a decision is reached. In so doing, there is the opportunity to weigh the benefits against the risks of any decision. When a unanimous decision cannot be reached, then a chance for an agreement based on majority decision could be an option. Third, collaboration was viewed to improve compliance and implementation. This was attributed not only to better decisions but also to a created sense of ownership and responsibility over a chosen course of action (Donahue and Zeckhauser, 2011).

Public health and safety is a shared goal of the government and the people it governs. The prevalent problem of SSFFC medicinal products entering the healthcare system with its negative impact is an area where multi-stakeholder collaboration could be explored as an effective approach to address the gaps and weakness in the prevailing system.

There are existing models of multi-stakeholders collaboration that are already in operation in other countries specifically focused on the problem of SSFFC products. This study explores the characteristics of these models based on the goals and objectives of collaboration, the involved stakeholders and their roles and responsibilities, the types of activities they engaged in and resulting outcomes. The aspect of sustainability and the overall strengths and weakness were also examined as permitted by data availability. At the country level, the presence adequacy of policy and legal framework focused on SSFFC medicinal products or counterfeit medicines is
also determined, as it is fundamental to the sustainability of any intervention against SSFFC medicinal products.

1. United States of America

As a result of globalization, developed countries like the United States also grapple with the problem of counterfeiting. While the extent of the problem may not be as high as those reported from developing countries, the danger of SSFFC products penetrating the health care system is a critical problem. The government had several regulatory actions to prevent the spread of counterfeiting in the country as tabulated below (Table 1):

Table 2. US Regulations to Control Counterfeiting

<table>
<thead>
<tr>
<th>Title</th>
<th>Purpose</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prescription Drug Marketing Act of 1987 (PDMA)</td>
<td>To prevent wholesale drug diversion</td>
<td>It requires state licensure of prescription drug wholesalers, regulates drug distribution and bans reimportation of drugs except when done by the manufacturer. This act also requires the purchaser must be provided with pedigree information which contains information about all parties involved in the transaction, date of each prior transaction and information about the drug.</td>
</tr>
<tr>
<td>Reducing Fraudulent and Imitation Drugs Act of 2006</td>
<td>To improve identity detection of drug products</td>
<td>It requires the use of radio frequency identification (RFID) or other track-and-trace technology, blister packaging and tamper-indicating technologies into the packaging of any drug.</td>
</tr>
<tr>
<td>Creation of the Food and Drug Administration (FDA) Counterfeit Drug Task Force</td>
<td>To lead in anti-counterfeiting actions</td>
<td>It covers reporting of suspected cases to FDA’s Med Watch System; This system provides the public and all stakeholders easily accessible information regarding SSFFC and safety alerts regarding medicines. It established the Counterfeit Alert Network (Ziance, 2013). This sustains the flow of communication among government and non-government stakeholders.</td>
</tr>
<tr>
<td>Ryan Haight Online Pharmacy Consumer Protection Act of 2008</td>
<td>To protect public from counterfeit medicines sold through the internet</td>
<td>It prohibits the delivery, distribution, or dispensing of controlled substances over the internet without a prescription (Chambliss, et al., 2010). The Act required the accreditation on online pharmacies to be differentiated from those who have not met government requirements for accreditation.</td>
</tr>
<tr>
<td>Adoption of the Normal Distribution Model for wholesale distribution by 18 States</td>
<td>To prevent entry of counterfeit prescription drugs</td>
<td>The wholesaler purchases prescription medicines solely from the manufacturer or designated agent of that manufacturer as required by law. If not, a documentation known as a pedigree has to be given to the buyer.</td>
</tr>
</tbody>
</table>

The US FDA is the lead agency coordinating the Counterfeit Alert Network (CAN), a coalition of health professionals and consumer groups tasked to:
• disseminate alerts about specific counterfeit incidents in the country and measures to take to minimize exposure to a wide audience;
• outline the roles and responsibilities of consumers, pharmacists, other health professionals, and wholesalers to identify counterfeit drugs, report suspect drugs, and prevent them from entering the US distribution system; and
• develop a network of national organizations, consumer groups, and industry representatives for wider information dissemination.

Members of this coalition include: American Academy of Family Physicians, American Academy of Nurse Practitioners, American Academy of Physician Assistants, American Medical Association, American Society for Aesthetic Plastic Surgery, American College of Clinical Pharmacy, Academy of Managed Care Pharmacy, American Pharmacists Association, American Society of Health-System Pharmacists, Healthcare Distribution Management Association, National Association of Pediatric Nurse Practitioners, National Association of Chain Drugstores, National Consumer League, National Community Pharmacists Association, Partnership for Safe Medicines, and Physicians Coalition for Injectable Safety. Any organization who wants to join the CAN should enter into partnership with FDA through a co-sponsorship agreement which outlines the roles and responsibilities of FDA and the participating organization (US FDA, 2009).

The MedWatch is another service provided by FDA. It is an internet-based reporting system (www.fda.gov/safety/medwatch/default.htm) for serious problems encountered with medical products and it is also a source of safety alerts regarding medicines.

There are other initiatives created by members of the CAN which also contributed to the goals of collaboration:

• HDMA, together with NABP, developed the Model Rules for Licensure of Wholesale Drug Distributors which calls for wholesalers to evaluate business partners. HDMA also conducted a research project with Rutgers University to develop requirements for data management and sharing in the healthcare supply chain.
• PhRMA initiated a voluntary program in which member companies notify FDA’s Office of Criminal Investigations of cases of discovered counterfeit products. PhRMA has also sponsored BuySafeDrugs.info which provides information to patients of risks associated with imported drugs and legal ways to save money on prescription drugs.
• NABP introduced the Verified Internet Pharmacy Practices Sites (VIPPS) program to accredit and certify online pharmacies that comply with criteria such as transmission of prescription information, patient data and privacy rights, authentication of prescription
drug orders, adherence to a recognized quality assurance policy, and provision of meaningful consultation between patients, and pharmacies.

- PSTF recommended an RFID phase-in plan with unspecified timelines.
- ASHP formulated a list of strategies that pharmacists can take to prevent acquiring counterfeit drugs and to report suspected cases.
- NACDS participated in the Jump Start multi-company project, which evaluated RFID functionality in the pharmaceutical supply chain.
- The Partnership for Safe Medicines formulated the SAFE DRUG checklist to help consumers identify and protect against counterfeits and the SafeMeds Alert System to inform enrollees of counterfeit alerts announced by FDA and other health agencies.
- Lastly, USP CI issued a quarterly matrix of drug quality problems and developed the manual, Ensuring the Quality of Medicines in Resource-Limited Countries: An Operational Guide (Ziance, 2013).

In general, the American model for multi-stakeholder collaboration, CAN has very clear goals. All key stakeholders are involved on a voluntary basis. The rules of engagement are clarified from the start, the roles and responsibilities are part of the co-sponsorship agreement which every organization has to be familiar with. FDA provides counterfeit alerts on a regular basis which the member organizations could disseminate to as many as possible. The presence of this coalition group does not discourage initiatives against counterfeit products by different organizations. In fact, sharing of resources and initiatives is possible in this model without deviating from the goals of the CAN. This model is illustrated in Figure 2.

![Figure 2. The US Counterfeit Alert Network Model](image)

It is noteworthy to mention that the United States has a separate model with regard to the regulation, enforcement and judiciary aspects of dealing with counterfeit medicines. This
concerns the handling of counterfeit cases from the time of detection, investigation, prosecution and resolution of the case. Within FDA, there are already several offices involved and they partner with other government agencies as well. While the reporting, monitoring and containment is within the purview of multi-stakeholders network like the CAN, another network is necessary to successfully implement the sanctions of the law against counterfeiting. Given that two-sided network, FDA has a good overview and control of the whole process. FDA is the depository of information on counterfeit cases which are valuable material for the production of educational materials for CAN partners. The relationship among these two networks and FDA is illustrated in Figure 3.

<table>
<thead>
<tr>
<th>Counterfeit Alert Network</th>
<th>Tasks</th>
<th>Lead Agency</th>
<th>Tasks</th>
<th>Intra-Government Agencies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professional Organizations</td>
<td>Reporting</td>
<td>Several offices</td>
<td>Detection Investigation</td>
<td>Federal Bureau of Investigation</td>
</tr>
<tr>
<td>Association of Distributors</td>
<td>Monitoring</td>
<td></td>
<td>Enforcement Case Resolution</td>
<td>Drug Enforcement Administration</td>
</tr>
<tr>
<td>Association of Retailers</td>
<td>Monitoring</td>
<td></td>
<td></td>
<td>Immigration and Customs Enforcement</td>
</tr>
<tr>
<td>Consumer Organizations</td>
<td>Education</td>
<td></td>
<td></td>
<td>Secret Service</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>State and local law enforcement</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>State and local regulatory agency</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Department of Justice</td>
</tr>
</tbody>
</table>

*Figure 3. FDA and Its Leadership Position in Multi-stakeholder Collaboration*

2. Nigeria

There are national laws which govern the safety of medicines in Nigeria. These are the Consumer Protection Council Act (1992), Counterfeit and Fake Drugs and Unwholesome Processed Foods Miscellaneous Provisions Act (1999), Decree on Marks (1990), Patent Decree (1990), and Patent Regulations (1971). In 1989, the Federal Military Government of Nigeria promulgated Decree No. 17, which prohibited the sale, distribution and display of counterfeit, banned, adulterated and fake medicines. To enforce this decree, the Nigerian Task Force was created, and Decree No. 25 of 1999 was promulgated to give power to the task force to close down all unregistered drug markets (Onwuka, 2011).

The Nigerian Task Force is the enforcement arm of the National Agency of Food and Drug Administration and Control (NAFDAC) and is divided into two classes: the Federal Task Force
and the State Task Force. Figure 4 shows the structure of the Nigerian Task Force on counterfeit medicines (Onwuka, 2011).

Both the Federal and State Task Forces are funded by the Ministry of Health and are given the power to close all unregistered premises until counterfeit medicines are removed or upon the order of the Minister of Health. The major activities of the task forces are:

1. to conduct raid in coordination with NAFDAC officials, a representative from the Pharmaceutical Society of Nigeria and Pharmacists Council of Nigeria, officials of the State Ministry of Health that includes a legal officer, and a public relations police officer; and
2. to educate the public through public awareness and enlightenment campaigns on the dangers of counterfeit medicines and to reduce demand for these medicines.

The task forces conduct post-marketing surveillance through routine and surprise inspections, and investigation upon receiving consumer complaints. In conducting inspections and raids, a pharmacist must be present. The senior pharmacist acts as the team leader (Onwuka, 2011).

Specifically, the Federal Task Force coordinates, directs and monitors the activities of the State Task Forces, and inspects ports or borders. It has authority on all the states with a notice to the particular State Task Force. On the other hand, the State Task Forces have the same duties with the Federal Task Force except its jurisdiction lies on the particular state they represent. They initiate public awareness programs and make ways to obtain intelligence reports (Onwuka, 2011).
The Nigerian Task Force model involves more of the military and less of the health professionals. There was no participation of professional organizations and the consumers. The regulatory, enforcement and education tasks are all assumed by the task forces. According to Erhun, et. al (2011), there is a lack of coordination, monitoring and control by the task forces leading to the continued proliferation of counterfeit medicines in Nigeria. However, efforts are being made to revive the State Task Forces through collaboration with government agencies and health professional organizations (Onwuka, 2011).

3. Indonesia

In Indonesia, there are laws and regulations governing counterfeit medicines – Law No. 1 on Criminal Act (1946); Law No. 23 on Health (1992); Law No. 8 on Consumer Protection (1999); Law No. 14 on Patent (2001); and Law No. 15 on Trademark (2001) (NADFC, 2007). In spite of these regulations, counterfeited medicines exist. They include lifestyle medicines, antibiotics and maintenance drugs. The proliferation of these questionable products are due to several factors: noncompliance to regulations that prohibit sale of medicines in unauthorized outlets, high cost of medicines, lack of public awareness, increased access to medicines sold online, difficulty in identifying counterfeit drugs, and inadequate penalties for counterfeiters (Akib, 2007).

In order to address the abovementioned factors, a collaboration of several stakeholders was set up by the government. Figure 5 shows the type of collaboration used by the National Agency for Drug and Food Control (NADFC). In this model, health care providers are at the center and they collaborate with government agencies, private companies and even with patients and consumer groups. It is expected that these stakeholders could influence both the supply chain and consumers regarding counterfeit medicines. Law enforcement agencies and the customs collaborate to strengthen the screening of counterfeit medicines on borders and ports to prevent entry of these medicines into the supply chain. When counterfeit medicines are reported to have entered the supply chain, the police and NADFC perform raids to seize these medicines. Trained inspectors and experts conduct investigation on suspected medicines. To influence consumer demand, partnerships with law enforcement agencies, both national and international, are developed. Also, public awareness is raised through brochures and television exposures (Akib, 2007).

The Indonesian model of collaboration yielded the following results: the needed technical support was provided, laboratory testing of samples were readily conducted by regulatory
authorities, and enforcers could employ force when needed, as sanctioned by existing laws and regulations. However, there are still problems encountered such as lack of reference standards in the National Quality Control Laboratories, lack of coordination among law enforcement agencies, lack of online system for information dissemination, non-implementation of existing laws, and mild penalties which may not limit the proliferation of counterfeit drugs (Onwuka, 2011).

Figure 5. Indonesia’s Mechanism of National Coordination (NADFC, 2007)

At present, Indonesia has a strategic plan on combating counterfeit drugs from the level of illegal manufacturers to the level of consumers. The planned activities include strengthening of the detection process for illegal drugs and their manufacturers, enhancement of public awareness about counterfeits, and improvement of collaboration with law enforcement agencies and other sectors. There is no documented evidence yet of the impact of this approach.

4. Costa Rica

As a country, Costa Rica is signatory to global trade agreements involving trademark, patent, intellectual property rights protection and as such, is bound to comply with many of their provisions. There are national laws that provide support to efforts against counterfeit drugs. These are: Consumer Protection Act, Intellectual Property Law, Legislation against the
Adulteration of Drugs, and the Patent Law. The proliferation of counterfeit medicines is a major problem in this country and other countries in South America. As part of its commitment to curb this problem, a Committee on Counterfeit Medicines was formed, composed of different stakeholders from the government and professional organizations. The stakeholders include the Ministry of Health, the Costa Rican Social Security System, the National Customs, the Parliamentary Commissioner for Administration, the Pharmaceutical Society, the Medical Society, the national and transnational pharmaceutical industries and the FDA. The committee used a collaborative approach in limiting counterfeit medicine proliferation through legislative, penal, administrative, disciplinary, professional and educational interventions. They are currently drafting and lobbying for a law against counterfeit medicines, and at the same time, is creating awareness on online procurement of medicines from unauthorized outlets (Onwuka, 2011).

5. Taiwan

Before 2003, Taiwan is the third largest counterfeit medicine market in South East Asia. At that time, reporting of counterfeit medicines was poor and deaths attributed to these products were not reported. The factors favoring the proliferation of counterfeit medicines in Taiwan were identified as lack of awareness both by the government and the public, light punishment by the law, and lack of political will to enforce regulation (Taiwan, 2011).

To address the problem of counterfeit drugs, several strategies were embarked on at the national level: (1) tightening of drug regulation, (2) improvement of drug distribution, (3) public education, (4) market surveillance, and (5) creation of an efficient reporting system. The Taiwan government strengthened its legal framework on counterfeit drugs through the amendment of the following:

- Regulation Amendments upgraded all penalties for manufacturing, importing, selling, dispensing, storage, transport and transfer of counterfeit drugs to a maximum of NT$10,000,000;
- Pharmaceutical Affairs Act provided additional provisions and stiffer penalties for various types of counterfeiters in the country;
- The penalty for violating the Trademark Law for the trademark of medicines was increased to a maximum of three year imprisonment and/or a fine of not more that NT$ 200,000;
- The Copyright Law's penalty was also increased to an imprisonment of not less than 6 months but not more than 3 years and/or a fine of NT$200,000; and
- The Criminal Law was also imposed on those who will forge the pharmaceutical companies’ names on the packaging boxes with an imprisonment of not more than 5 years.

As a result of these regulatory reforms, the number of sentenced cases of counterfeiting increased from 126 in 2004 to 384 in 2008.

In October 2003, a Cross-Departmental Task Force was formed by the government, as shown in Figure 6. The Task Force is composed of the Department of Health, Ministry of Justice, National Police Agency, District Court, Bureau of Investigation, Custom Office, Ministry of the Interior, Taiwan High Prosecutor Office, Directorate of Customs, National Communications Commission, Intellectual Property Office, Ministry of Finance and several industry groups (IRPMA, TPMMA, CAPA, TPMDA, Pharmacists Association). This task force aims to integrate the resources and skills of the stakeholders, to increase the number of joint inspections and to create a list of blacklisted products and companies. The group enhanced the reporting system through a toll-free service phone number and a feedback email (Onwuka, 2011).

![Figure 6. Framework of the Cross-Departmental Task Force on Counterfeit Medicines in Taiwan](image)

The Taiwan model of collaboration shows delineation of functions among the stakeholders. Understanding the specific contribution of each sector provides focus in their involvement and allows coordination to happen when working on a particular initiative. The duties of the collaborative team composed of government agencies during the government crackdown on illegal drugs are provided in Table 3.
Table 3. Duties of Government Agencies Involved in the Crackdown on Counterfeit Medicines

<table>
<thead>
<tr>
<th>Authority</th>
<th>Duties</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Health</td>
<td>• Launch a joint campaign of crackdown on illegal drugs</td>
</tr>
<tr>
<td></td>
<td>• Implement training program for crackdown on counterfeiting drugs</td>
</tr>
<tr>
<td></td>
<td>• Supervise local health authorities to inspect illegal drugs on the market</td>
</tr>
<tr>
<td></td>
<td>• Verification and analysis of illegal drugs</td>
</tr>
<tr>
<td>Ministry of Justice</td>
<td>• Speed up the legal process of reported cases of counterfeiting drugs</td>
</tr>
<tr>
<td></td>
<td>• Increase the penalties imposed on the prosecuted</td>
</tr>
<tr>
<td>National Police Administration</td>
<td>• Strengthen the investigation and hunting down of illegal drug cases</td>
</tr>
<tr>
<td>Directorate General of Customs</td>
<td>• Tighten up the custom check for smuggled drugs</td>
</tr>
<tr>
<td></td>
<td>• Send suspected cases of counterfeit drugs to authorities for verification, and subsequently refer to the prosecutorial system for investigation</td>
</tr>
</tbody>
</table>

Since Taiwan is not a WHO member country, the Taiwan Medical Products Anti-counterfeiting Task Force (TMPACT) was formed, which functions like the WHO IMPACT. It is a non-profit, non-government organization that collaborates with the Department of Health on its fight against counterfeit medicines. TMPACT aims to provide education programs, to aid in counterfeit drug detection and development of detection techniques, to attend global anti-counterfeiting meetings, to estimate counterfeit drug value in the market, and to foster international collaborations. Several strategies were performed to attain these objectives that include the establishment of a Medication Identification System in the DOH website, training of inspection personnel with the latest technologies, organizing activities that promote drug safety, publishing a counterfeit drug detection manual, organizing a joint market inspection at least once a month and an onsite testing of medicines using near-infrared technique (Onwuka, 2011).

In general, there were aspects of collaboration that need improvement such as: (1) coordination among the different government agencies, which may be due to the weak leadership of the DOH and the lack of incentives for the investigators; (2) market data gathering due to the nonexistence of a central monitoring system and an inconsistent definition for counterfeit medicines; (3) light court sentences for counterfeiters; and (4) quality of investigations (Taiwan, 2011).
6. European Union

The European Union (EU) is made up of 28 countries, each with its own sovereignty. The European Medicines Agency is responsible for the implementation of directives under EU legislation. It claims that EU has a strong legal framework for the licensing, manufacturing, and distribution of medicines. In 2011, it strengthened the protection of patients and consumers by adopting a new Directive on Falsified Medicines for Human Use. The directive aims to prevent falsified medicines from entering the legal supply chain and reaching patients. It introduced harmonized safety and strengthened control measures across Europe grouped under 4 pillars: safety features of medicines; supply chain and good distribution practice; active substances and excipients; and internet sales (European Medicines Agency, 2015). Other related issuances of the Agency include: Directive 2011/62, Commission Implementing Regulation EU No 699/2014, and Directive 2004/48 on IPR.

In Europe, multi-stakeholder collaboration concerning falsified and counterfeit drugs is in the area of communication. There are two strategies employed: (1) the proactive information strategy; and (2) the reactive communication strategy. The proactive information strategy makes use of campaigns and awareness programs to influence people’s behavior on medicine use. This strategy includes the public, patients, health care professionals, the medicines’ production and distribution chain, and the media as its stakeholders. Heading this group is the Drug Regulation Authority (DRA), which also serves as the sender of internal information and recipient of information from external sources. The DRA initiates an information campaign for the general public, which focuses on buying medicines at authorized pharmacies only and reporting of ineffective medicines and quality problems to a pharmacist. In some cases, joint information campaigns may also be prepared by other stakeholders where the DRA can participate (EDQM, 2008).

On the other hand, the reactive communication strategy starts when a suspected or verified counterfeit medicine enters the distribution chain. Figure 4 shows the flow of information using a multi-stakeholder approach. In this strategy, the DRA and the Ministry of Health (MoH) organize a taskforce of experts depending on a case. and a two-way flow of information is established. Proactively, the health care professionals provide care and relay information to patients. The general public acting responsibly, heed advice from health care providers. The members of the media cooperate with DRA and MoH and relay important messages through various modes of mass communication. As a reactive form of communication, the manufacturers and distributors recall and isolate the products suspected to be counterfeit, inform the DRA and
MoH of the recalls, and replace the counterfeited products with authentic products, as needed (EDQM, 2008).

Figure 7. Information Flow in the Proactive/Reactive Communication Strategy Using a Multi stakeholder Approach (EDQM, 2008)

The European model of collaboration is more of a fluid relationship of all the stakeholders in the aspect of communication which are all connected through the taskforce which sets the direction of the collaboration. It differs from the features of the other approaches where stakeholders are made part of the group according to specific functions each play regarding counterfeit medicines. This model describes more the flow of communication depending on the goal. Proactive strategy is directed towards improving public awareness about counterfeit medicines through transmission of information from the taskforce to distribution chain, healthcare professionals, media and general public and patients. Reactive information sharing happens when there are actual counterfeit cases that require the information from the distribution chain to task force who will coordinate with the enforcement group.

An example on how this model works is in the case of the United Kingdom Department of Health, Social Services and Public Safety (DHSSPS). The department had formulated guidelines on internet purchase of medicines for the general public and health professionals. It also has a list of registered online medicine providers. The guidelines and other information are made available to their target recipients and could be accessed through the website, www.dhsspsni.gov.uk. The website provides avenue for reporting from the public and it has contact information on a point person within the Medicine Enforcement Services.
B. Situational Analysis of SSFFC Monitoring, Reporting, and Containment in the Philippines

A series of key informant interviews (KIIs) were conducted during the period of August-September 2015 to find out the status of monitoring, reporting, and containment of SSFFC medicinal products in the country. There was a total of 53 letters sent to different government agencies and private organizations but only 28 key informants consented to be interviewed (Appendix 1). Appendices 2 and 3 are the interview schedules used for gathering information from the key informants. The set of questions for government agencies differs from the set of questions for private organizations or groups. The interview schedule is accompanied by a consent form for the respondent (Appendix 4). The number and the institution represented by the KII respondents are given in Table 4.

Table 4. Institutions which Participated in the Key Informant Interviews

<table>
<thead>
<tr>
<th>Institution/Group</th>
<th>Number of Respondents</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA</td>
<td>2</td>
</tr>
<tr>
<td>PDEA</td>
<td>1</td>
</tr>
<tr>
<td>CIDG</td>
<td>1</td>
</tr>
<tr>
<td>DPIO</td>
<td>1</td>
</tr>
<tr>
<td>ACCU</td>
<td>1</td>
</tr>
<tr>
<td>AFCCU</td>
<td>3</td>
</tr>
<tr>
<td>NBI</td>
<td>1</td>
</tr>
<tr>
<td>BOC</td>
<td>1</td>
</tr>
<tr>
<td>IPO</td>
<td>1</td>
</tr>
<tr>
<td>Local Government Unit (LGU) – Cavite</td>
<td>2</td>
</tr>
<tr>
<td>Regional Government Offices – CHD, FDA, NBI (Baguio City, Cebu City, Davao City)</td>
<td>6</td>
</tr>
<tr>
<td>Manufacturers</td>
<td>2</td>
</tr>
<tr>
<td>Distributors</td>
<td>3</td>
</tr>
<tr>
<td>DSAP</td>
<td>1</td>
</tr>
<tr>
<td>PMA</td>
<td>1</td>
</tr>
<tr>
<td>PPhA</td>
<td>1</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>28</strong></td>
</tr>
</tbody>
</table>

The stakeholders are representatives of government regulatory agencies, government enforcement offices, pharmaceutical industry, professional organizations, and retailer group. There were three government offices - Department of Trade and Industry, Department of Justice, Supreme Court- which declined participation since they reasoned out that they do not
deal directly with counterfeit medicines and that DOH-FDA is the lead agency for counterfeit drugs.

Government agencies’ representatives were asked regarding their mandate and responsibilities regarding SSFFC. Their responses are as follows:

- FDA is the agency mandated to lead control of counterfeit drugs based on the IRR of the Special Law on Counterfeit Drugs (RA 8203). According to the IRR, the functions of FDA are monitoring; examination of suspect counterfeit products; responding to reports of suspect counterfeit medicines; and submission of result of examination for administrative proceeding. The FDRO has authority to inspect its licensed facilities, coordinate with law enforcers, and maintains website to disseminate updates and public warnings including information on counterfeit products.

- PDEA is involved in law enforcement, monitoring and control of counterfeited dangerous drugs. It has enforcement or operative unit and intelligence unit within the agency so it can conduct buy bust operation without relying on external enforcement agencies. It conducts surveillance and works with FDA in monitoring products. It has its own laboratory to conduct tests of suspect counterfeit dangerous drugs.

- The PNP and its various units (CIDG, DPIO, ACCU, AFCCU) are mainly involved with law enforcement, receiving and verification of reports of suspected counterfeit drugs. They have police power and can undertake or execute operation/raids. They coordinate with FDA regarding operations and laboratory testing of suspect counterfeit drugs.

- NBI is into investigation of suspect counterfeit cases. They inform and coordinate with FDA regarding reports on suspect counterfeit products. Together with FDA, they perform investigation and conduct buy bust operation.

- The PNP ACCU investigates cases of suspect counterfeit products sold through the internet. However, their work is limited only to online selling of counterfeit products by sellers who are covered by Philippine laws such as call centers and other companies registered in the country. They have no jurisdiction on entities and products that are sold from abroad and are marketed online by foreign companies.

- The BOC protects entry points from imported counterfeit products. Freight containers arriving from foreign countries are checked for unregistered products, fake sources of products and false documentation; It coordinates with FDA regarding confirmation of suspect counterfeit medicines.

- The IPO monitors and controls counterfeit products in relation to intellectual property issues. Particularly, it handles conflict and resolution of intellectual property cases. It has enforcement and visitorial powers such that they can perform raid of a suspected
establishment. The limitation though is that they only deal with intellectual property rights violation rather than the public health aspect of counterfeit products.

- The local Government Health Unit in a city made no mention of any mandate regarding counterfeit medicines. In fact, there is a request that they be informed of how to identify counterfeits and also that they be guided to prevent counterfeit medicines from being procured by their hospital.

- The Local Government (City Officer) has no mention of any mandate regarding counterfeit medicines. There was a suggestion that they need more information about counterfeit drugs and that coordination could be made with them by FDA to strengthen efforts against counterfeit medicines.

- The Regional Government Offices (DOH) are not involved in major anti-counterfeit activities since according to them, this function was already assumed by FDA. However, they could help increase public awareness about counterfeit drugs through information dissemination.

- The Regional Government Offices (FDA) ensures that health products are safe, quality and effective by virtue of RA 5921, RA 8203, RA 9502, RA 9711. Their work involves regular inspection of regulated establishments and post marketing surveillance of registered products. In case of suspected counterfeit drugs, the office coordinates with NBI for enforcement. They collect samples of suspected counterfeit products and send them to Central Office for laboratory testing. They serve Notice of Violation to erring establishments and has the power to seize products. Post warnings and advisories are posted in the FDA website and further disseminated through the regional offices.

In addition to their respective mandates, some government agencies have standard operating procedures in carrying out their responsibilities. They were also able to identify encountered barriers in carrying out their specific roles on counterfeit medicinal products. These barriers are enumerated in Table 5.
Table 5. Identified Barriers by Different Government Agencies

<table>
<thead>
<tr>
<th>Agency</th>
<th>Barriers</th>
</tr>
</thead>
<tbody>
<tr>
<td>FDA</td>
<td>The agency has a unit with limited manpower to handle counterfeit medicines reports and coordinate search and seize operation. Also, there is limited number of inspectors to cover all regulated establishments. Lack of resources and heavy workload are some of the major internal barriers identified by respondents. There is a need for standard operating procedures concerning SSFFC medicinal products. Counterfeit monitoring and control are not yet a priority of the agency.</td>
</tr>
<tr>
<td>PDEA</td>
<td>The scope of function is limited only to dangerous drugs. The work is intelligence-based and the agency depend heavily on their own intelligence group to be able to execute an operation. Manpower is currently inadequate, if the work has to be expanded to all areas of the country.</td>
</tr>
<tr>
<td>PNP</td>
<td>The agency cannot start their function without an informant and/or complainant and the case cannot stand without them. If there was a suspect shipment from the port, the police cannot simply demand inspection when the shipment already passed customs. The release of search warrant takes time and often, the suspects and the products will no longer be found when the warrant is served. The agency does not have the budget needed for testing suspect products from facilities not licensed by FDA. At present, there is no warehouse for confiscated products. There is delay in the release of lab analysis from FDA laboratory. Counterfeit medicines procured from foreign suppliers through internet are not covered by cybercrime unit as cases are limited only to those committed by Philippine-registered online providers of goods and services.</td>
</tr>
<tr>
<td>BOC</td>
<td>Customs has limited technical capacity for detecting counterfeit drugs due to absence of high technology equipment. It lacks human resources to man 17 entry ports. There is no other agency allowed to work within the area of responsibility of BOC unless authorized by the Commissioner. The work is limited to checking registration and documentation and not the technical examination of products that enter through the ports.</td>
</tr>
<tr>
<td>IPO</td>
<td>The work is limited to counterfeit cases in which intellectual property is involved. The lack of resources is still a major concern.</td>
</tr>
<tr>
<td>Local Government Health Unit</td>
<td>There is lack of knowledge among end-users, and Bids and Awards (BAC) members on quality aspect of medicine. There is poor procurement system where clinicians are not involved at all in giving feedback about the clinical efficacy of medicines procured. There is a lenient implementation of rules of the Procurement Act (RA 9502) within the institution. There is no formal reporting mechanism. There is also lack of pharmacists in the health facility.</td>
</tr>
<tr>
<td>Local Government Office (City Hall)</td>
<td>The City officials are not well-informed on counterfeit drugs. There seems to be a missing link between the DOH and the city hall in terms of inspection and inventory of drugs. They are not formally informed of anti-counterfeit activities in their area.</td>
</tr>
<tr>
<td>Regional Center for Health Development</td>
<td>The role of CHDs in counterfeit medicines is not well-defined. Proper coordination with FDA is needed. The training of the agency's personnel on counterfeit drugs was not conducted yet.</td>
</tr>
<tr>
<td>Regional Government Office (FDA)</td>
<td>Presence of sari-sari stores selling medicines remains unregulated. There is a need for LGU-FDA collaboration regarding sale of medicines in various outlets. The problem of lack of resources – manpower, transportation, accommodation exists. Consumers are afraid to report. There is no local laboratory to provide quick results of testing. There is no proper coordination with other agencies who are also involved with efforts against counterfeit drugs. The geographic location is challenging in some regions. Under the table transactions still happen. The FDROs become jack of all trades in terms of assignments and responsibilities.</td>
</tr>
<tr>
<td>Regional Government Office (NBI)</td>
<td>The country has vast coastline for entry of products. Small pharmacies and Chinese drugstores do not follow the law strictly. There is no local laboratory which could establish authenticity of suspect counterfeit products.</td>
</tr>
</tbody>
</table>
The KII also explored the current roles and responsibilities of non-government stakeholders in combating counterfeit medicinal products. Their responses are as follows:

- The Philippine Medical Association (PMA), the national organization of physicians is mainly involved in reporting and public education. It is engaged in advocacy groups on counterfeit drugs like *Samahan Laban sa Pekeng Gamot*, Safe Medicines Network, and engage in school caravans to educate students on these medicines, and collaborate with FDA on their counterfeit program.

- The Philippine Pharmacists Association (PPhA) basically provides continuing education of pharmacists on counterfeit medicines and is also involved in reporting based on information from members. It is represented in the advocacy groups like *Samahan Laban sa Pekeng Gamot*, Safe Medicines Network, and in activities relating to combating counterfeit medicines problem. It provided resource persons to provide information in both television and radio platforms. Recently, it has produced a set of modules on counterfeit medicines, *Counterfeit Medicines Education and Vigilance in the Health Professions*, for use by health professionals (PPhA, 2015).

- Drugstore Owners Association of the Philippines (DSAP) An association of retailers, works mainly on education of drugstore owners and other pharmacy personnel. The organization was likewise represented in the Safe Medicines Network and the former *Samahan Laban sa Pekeng Gamot*.

- Manufacturers, whether multinational or local, monitor their products in the market as part of their post-marketing surveillance. In coordination with FDA and enforcer agencies, they take part in the investigation process of reported counterfeiting of their respective products and provide reports to FDA regarding quality problems with their own products.

- Distributors (distributor, wholesaler) provide education to drugstore personnel through seminars, give feedback to suppliers, and assure safety and authenticity of products being distributed. They report suspected counterfeit cases and ensure strict compliance to regulatory requirements for their products.

Non-government stakeholders were also interviewed regarding their perceived internal weaknesses and external barriers why the problem of counterfeit medicines still prevails in the country. To this, they were able to provide relevant responses which are grouped as follows (Table 6):
Table 6. Perceived Weaknesses and Barriers by Non-government Stakeholder

<table>
<thead>
<tr>
<th>Stakeholders</th>
<th>Internal Weaknesses</th>
<th>External Barriers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Professional Organizations</td>
<td>There are no guidelines on how they could effectively engage in anti-counterfeit medicine activities. There is no group within the organization that specifically deal with counterfeit drugs. Professionals also fall victim to counterfeit products due to limited information about them.</td>
<td>There is prevailing lack of public education. Some doctors there is laxity or lack of monitoring by the government. There is lack of participation or willingness of the public and professionals to report. Dispensing doctors are also targeted by suppliers of counterfeit drugs. Peddlers are selling medicines to outlets. The lack of concern among health professionals result to counterfeit medicines reaching the patients.</td>
</tr>
<tr>
<td>Pharmaceutical industry</td>
<td>The industry keep data on counterfeit cases confidential to somehow protect sales of genuine products. They tend to rely primarily on reports rather than perform proactive search.</td>
<td>Suppliers of counterfeit medicines are barely penalized. FDA has no measure to control re-registration of offenders (counterfeiters) using another name. There is apparent security risk for individuals who report counterfeiting activities. At the consumer level, there is inadequate technology for monitoring pharmaceutical products. Campaign activities against counterfeit products are wanting. Smuggling arises since there is limited checking at the ports of entry. Parallel importation could be another source of counterfeits. Sales of medicines through the internet remains unregulated. There is fear of reporting and investigation among consumers. Poor inter-agency collaboration remains a barrier to coordinated activities. Current government system and processes are deemed not 100% fool-proof. There is pressure on the market for very low prices which favors outsourcing. There is also an increase demand for pharmaceutical products not available in the country and so importation ensues. The collaboration with civilians is lacking; FDA has inadequate number of personnel to handle anti-counterfeit activities.</td>
</tr>
<tr>
<td>Retailers Organization</td>
<td>There is fierce competition among retailers and so they tend to purchase at low cost to compete. Retailers do not have enough information on suppliers especially imported medicines. The existing technology in pharmacies is not capable of detecting counterfeits. Drugstore owners rarely report counterfeit cases to FDA.</td>
<td>There is inadequate inspection of drug outlets by FDA. Peddlers sell medicines without being caught. There is lack of public awareness about counterfeits. Selling of medicines in sari-sari stores is unregulated. There is no strict implementation of the law including regulation of Chinese drugstores. There is late inspection and slow response from reporting by FDA which they attribute to inadequate personnel.</td>
</tr>
<tr>
<td>Health Facilities</td>
<td>There is lack of knowledge among endusers and BAC regarding quality of medicines. At the local health care facilities, there is poor procurement system and the law is not strictly followed. There is no formal reporting mechanism regarding medicines. The number of pharmacists is inadequate.</td>
<td>Procurement of medicine is a political issue. The operation of internet pharmacies is unregulated. Medicines sold in sari-sari stores never get inspected by FDA.</td>
</tr>
</tbody>
</table>
It was evident that different stakeholders perform some tasks in relation to the problem of counterfeit medicines. There was no measure, however, whether they are able to achieve according to a set of performance standards or expected outcomes (Figure 8).

![Figure 8. Summary of weaknesses and barriers from government and non-government stakeholders](image)

As the lead agency identified by law to handle counterfeit medicines issues and as the agency expected by all stakeholders to direct SSFFC-related programs, FDA was not able to exercise its full mandate. There are also inadequacies with how the different stakeholders connect with the issues and problem on counterfeit medicines. From the government side, different government agencies have varying degrees of involvement. Each agency admits to its own deficiencies and as such, was able to identify internal barriers which affect their performance of their duties. They were also able to describe factors which account for the proliferation of SSFFC in the market. Several had alluded to the problem of weak implementation of the special law on counterfeit drugs and the recognition that the regulatory agency has a larger role to address the problem at hand.

In addition to the KII, a telephone survey of some consumer groups, patient groups and varied non-government organizations was made. This is to determine if there is any group among them which took on counterfeit medicinal products as their advocacy. These groups were contacted by phone and were asked if their organization is engaged in any activity related to counterfeit medicines. Of the total 60 respondents representing more than 40 organizations, only one is
involved with increasing public awareness regarding counterfeit medicinal products and another one promoting the rational use of medicines. It seems that currently, there is no consumer group assuming counterfeit medicines as its major advocacy.

On hindsight, there were two advocacy groups, formed sometime between 2008 and 2010, that were active in anti-counterfeit medicines activities – Samahan Laban sa Pekeng Gamot and the Safe Medicines Network. The major activities of these groups were: promotion of public and group awareness about counterfeit medicines through seminars and representation in media forums; provision of venue for discussing issues like anti-counterfeit technology, counterfeit prevention methods, and common industry problems; networking with other groups like IMPACT and Interpol. The groups were made up of representatives from pharmaceutical industry, professional organizations, distributors, retailers' organization, large chain pharmacies, and consumer groups. Both advocacy groups were convened by representatives of the pharmaceutical industry. The Samahan Laban sa Pekeng Gamot in coordination with FDA was responsible for lobbying and the subsequent approval of Proclamation No. 2082, series of 2010, known as the National Consciousness Week Against Counterfeit Medicines (NCWACM).

The Samahan Laban sa Pekeng Gamot and the Safe Medicines Network are both inactive for the last two years. The existence of these multi-sectoral groups is highly dependent on the initiatives of the convenor organization and their purpose for meeting other stakeholders. Sustaining this alliance requires policy and legal framework, logistics, and government leadership. The FDA was a member of these initiatives.

From 2013 up to the present, the FDA assumed the organization of activities for the NCWACM and involves various stakeholders to participate in these activities. A symbolical commitment of various government agencies and non-government organizations and groups has been held regularly during the NCWACM to seek support for the fight against counterfeit medicines. However, it was only last year when planning for a formal organizational structure, process, and programs was embarked on to sustain such commitment.

In 2014, the FDA initiated the convening of various stakeholders to establish the Coalition for Safe Medicines (CSM). The coalition has well-defined functions – public information and advocacy, research and policy development. The coalition’s activities in relation to their public information and advocacy are: development of Information, Education and Communication (IEC) materials; utilization of different media including social media to disseminate information; conduct of dialogues with the public through symposia, fora, and other similar activities;
engagement of other regulatory and enforcement agencies to align policies and facilitate sharing of relevant information; and engagement of healthcare professionals and health facilities to establish networks for collaborative work.

For their research function, the CSM is expected to carry out research in the following areas: incidence and prevalence of counterfeit medicines in the country; scope and extent of counterfeit medicines proliferation; impact of counterfeit medicines (e.g. economic impact, health-related impact); and efficient and effective networks for collaboration (e.g. development of effective systems of reporting and feedback). The outcomes of research are expected to direct the development of new policies and amendment of existing policies. To add, the research data could also be utilized in IEC materials development.

CSM is composed of representatives from government regulatory and enforcement agencies, local government leagues, and relevant organizations, associations and institutions. To date, the members are: BoC, DTI – Consumer Protection Group, FDA, IPOPhil, Philippine Center on Transnational Crime, PNP – Criminal Investigation and Protection Group Anti-Fraud and Commercial Crimes Unit, PDEA, NBI, DOH Pharmaceutical Division; Leagues of Cities, Municipalities, and Provinces as well as Union of Local Authorities of the Philippines; DSAP, DOH League of Pharmacists, Manila Pharmacists Society, Medicines Transparency Alliance Philippines, PHAP, Philippine Alliance of Patient Organizations, Philippine Association of Colleges of Pharmacy, Philippine Association of Pharmacists in the Pharmaceutical Industry, Philippine Chamber of the Pharmaceutical Industry, Inc., Philippine Medical Association, Philippine Nurses Association, Philippine Pharmaceutical Manufacturers Association, Philippine Pharmacists Association and the Philippine Society of Hospital Pharmacists. Commission on Higher Education, Dangerous Drugs Board and the DOH National Center for Health Promotion.

The Coalition for Safe Medicines was formally launched during the celebration of the NCWACM last November 23, 2015. The officers were introduced together with the members of the coalition. The functions of CSM are in harmony with the expected functions of multi-stakeholders collaboration models in that the major function is the promotion of greater public awareness and education on counterfeit medicines. The research and policy development are added functions. Research may require some funding for it to be sustained. Given its wide composition involving government and non-government entities, there is a wider reach of stakeholders compared to other country models. The organization, however, does not highlight the leadership status of FDA as mandated by law. The FDA instead will act as the Secretariat and
would share in the hosting of meetings and related expenses. The leadership of the CSM is currently held by a non-government representative (Figure 9).

![Organizational Structure of the Coalition for Safe Medicines](image1)

**Figure 9.** The Organizational Structure of the Coalition for Safe Medicines

C. Strengths, Weaknesses, and Areas for Improvement of the National Regulatory Framework

The analysis of the national regulatory framework for SSFFC problems will focus on the **structure, functions, processes and outcomes of implementation** (Figure 10).

![Structure-Process-Outcomes Method of Analysis](image2)

**Figure 10.** The Structure-Process-Outcomes Method of Analysis
While the Donabedian model has been used as a framework to evaluate the quality of health care and its impact, it can also be used in policy analysis, specifically those policies in relation to SSFFC. Operationally, the *structure* in this case will refer to the organizational structure of the implementing agency in relation to its mandate; the *processes* pertain to the processes and procedures that should be in place to accomplish the goals of the policy; and the *outcomes* refer to the goals of the policy implementation which are the promotion and protection of the right to health of the people, specifically their protection against counterfeit drugs. In more practical terms, this could be interpreted as (1) increase in the number of reports received, (2) increase in the number of counterfeit cases resolved or prosecuted, (3) increased level of public awareness on counterfeit medicines, and (4) increase in the number of advocate stakeholders for counterfeit medicines and ultimately, (5) the absence or significant reduction of counterfeit medicines in the market.

**RA 8203 (Special Law on Counterfeit Drugs)**

*Structure*

The presence of a law specific to the control of counterfeit drugs is considered advantageous for the Philippines. This is in line with the framework described by Seiter (2010). The overall hierarchy composed of laws, regulations, and implementing agencies in the pharmaceutical sector (Figure 11) is essential for the pharmaceutical industry to be regulated properly. Effective regulation of the pharmaceutical sector could be measured in terms of high and consistent quality of drugs in circulation, absence of an informal drug market with unlicensed sellers and drug peddlers, and by the absence of counterfeit, nonregistered and substandard drugs from the market, among others.
Based on the above framework, the Philippine Constitution has the provision to protect citizens’ right to appropriate treatment including access to safe, effective and quality medicines. The laws, RA 3720 (Food, Drugs and Cosmetics Act) and RA 9711 (The FDA Act of 2009) mandated the Food and Drug Administration to be the guardian of quality and safety of medicines. The monitoring, reporting and containment of SSFFC is covered by RA 8203 and its Implementing Rules and Regulation (IRR). It is also supported by provisions of other laws and regulations such as the Criminal Code (1980), RA 6675 (Generics Act of 1988), RA 7394 (Consumer Act of 1996), RA 3792 (E-Commerce Law of 2000), RA 8293 (Intellectual Property Code of the Philippines of 2000), RA 9502 (Cheaper Medicines Act of 2008) and RA 9711 (Food and Drug Administration Act of 2009). Using the above regulatory framework for the pharmaceutical sector, Philippines has several policies that should empower implementing agencies and groups to achieve effective regulation of the industry. It was observed by Seiter (2010), though, that while high income countries may have better control of the counterfeit drug problem, low- and middle-income countries often lack the resources to control their markets and enforce their laws, even when their laws cover this important area.

The lead agency identified to implement RA 8203 was the Bureau of Food and Drugs (BFAD) in consultation with the Department of Health. The implementing rules and regulations (IRR) specified BFAD’s main functions: monitoring of counterfeit drugs, accreditation of complaints desk, and administrative action.
With the enactment of RA 9711 in 2009 and the subsequent reorganization of BFAD into FDA, there were major changes in the names, functions and scope of responsibilities of the offices and units under BFAD. It followed that the offices mentioned in the law as shown in the procedure for monitoring counterfeit drugs no longer exist (Table 6). The previous functions on counterfeit drugs, however, were assumed by current offices and units. This discrepancy need to be addressed by amendment to RA 8203.

The Special Law on Counterfeit Medicines and its IRR did not identify a specific implementing unit under FDA. At present, this role is assumed by a unit under the Center for Drug Regulation and Research (CDRR) which also handles the pharmacovigilance program. With limited expertise, manpower and resources provided to this unit, the mission of effectively addressing the SSFFC problem at the national level would be significantly hampered.

Processes

The monitoring procedure for counterfeit drugs described in the IRR of RA 8203 outlines the steps, responsibilities, and offices associated with the tasks and even timeframe of some of the steps in monitoring (Table 7). All the offices had existed in the previous organizational setup of FDA. The tasks, however, were being carried out by current offices which are not yet identified in any policy concerning counterfeit medicines.

<table>
<thead>
<tr>
<th>Step</th>
<th>Activity</th>
<th>Person/Office-in-Charge</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>During inspection of factory, warehouse, establishment or vehicle, finished or raw materials, containers and labeling, conduct an inventory, segregate and seal the suspected stocks, and collect samples for examination to determine whether counterfeit or not.</td>
<td>Food and Drug Regulatory Officer (FDRO)</td>
</tr>
<tr>
<td>2</td>
<td>Immediately upon return to his/her office, the FDRO concerned shall submit the samples to either the LSD or PSD for their examination or evaluation.</td>
<td>FDRO, LSD, PSD</td>
</tr>
<tr>
<td>3</td>
<td>Within twenty (20 days), the genuineness and authenticity has to be determined either by:</td>
<td>LSD, PSD, registered brand owner of the suspected counterfeit</td>
</tr>
<tr>
<td></td>
<td>a. Laboratory testing</td>
<td></td>
</tr>
<tr>
<td></td>
<td>b. Physical examination, the result is a certification of findings</td>
<td></td>
</tr>
<tr>
<td></td>
<td>c. Referral to the registered brand-owner of the suspected counterfeit drug to certify whether or not the suspected drug product has been manufactured, imported and/or distributed by them; or whether they own the Lot Number and Expiry Date of the same suspected drug product. The certification issued by the registered brand-owner shall be supported by the batch, production and distribution records. However, the brand-owner's certification shall be validated by the PSD for evidentiary purposes.</td>
<td></td>
</tr>
</tbody>
</table>

Table 7. Monitoring Procedure for Counterfeit Drugs in the Market
<table>
<thead>
<tr>
<th>Step</th>
<th>Activity</th>
<th>Person/Office-in-Charge</th>
</tr>
</thead>
<tbody>
<tr>
<td>4</td>
<td>a. When the result of examination shall confirm that in fact the drug product is counterfeit, the LSD or PSD shall forward the result of examination to the LICD for a motu proprio investigation.</td>
<td>LSD, PSD, LICD</td>
</tr>
<tr>
<td></td>
<td>b. When the result of examination shows that the drug sample is genuine, the PSD or LSD shall forward the report of examination or evaluation to the FDRO through his/her Division Chief</td>
<td>PSD, LSD, FDRO, Division Chief, Regional Food and Drug Section, Regional Director</td>
</tr>
<tr>
<td></td>
<td>• If the sample products are within the Metro Manila area, the Regulation Division concerned shall, within sixteen (16) working hours from receipt of such report, notify the outlet or the communication available. However, only an FDRO can unseal the suspected product before it can be released for sale.</td>
<td>Regional Director</td>
</tr>
<tr>
<td></td>
<td>• When the sample products are located outside the Metro Manila area, the Regulation Division concerned shall send a notice to release the products to the Food and Drug Section having territorial jurisdiction over the same through the Regional Director within sixteen (16) working hours from receipt of the notice. The FDRO assigned in the said province shall, within sixteen (16) hours from receipt of the notice, unseal the suspected drugs for sale.</td>
<td>Regional Director</td>
</tr>
</tbody>
</table>

Accreditation of complaints desk is another function of BFAD (FDA) mentioned in Rule III, Section 6 of RA 8203. "Upon application by an interested pharmaceutical association, BFAD shall accredit complaint desks that may be established by any pharmaceutical organization or association. The desk shall receive and refer verifiable letter of complaint or information from any of its members about counterfeit drug products. Any letter of complaint or information referred to BFAD by such complaint desk shall be processed in accordance with Section 2 of Rule IV hereof." However, based on observation and interaction with officers from the professional and retailers association, they were neither informed nor aware of any information from FDA regarding complaint desks on counterfeit medicines. It is presumed that this aspect of the IRR was not implemented at all. This should have facilitated better reporting of suspect counterfeit medicines.

The procedure for lodging administrative complaints was also indicated in the IRR under Rule IV, Sections 1-5. The procedure is contained in Table 8.
Table 8. Procedure for Filing Administrative Complaint Depending on the Complainant

<table>
<thead>
<tr>
<th>Step</th>
<th>Activity</th>
<th>Person/Office-in-Charge</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Any person may file a complaint whether in an affidavit or letter form with the BFAD *LIC or in any BFAD Accredited Complaint Desk.</td>
<td>Complainant, LIC, Accredited Complaint Desk</td>
</tr>
<tr>
<td>B</td>
<td>A drug establishment or a registered brand owner may file an administrative action against any person or establishment for any acts in violation of RA 8203 through an affidavit of complaint.</td>
<td>Complainant, LIC, Accredited Complaint Desk</td>
</tr>
<tr>
<td>C</td>
<td>A consumer, physician-prescriber or other interested party other than the registered brand owner may file a letter of complaint or information about a suspected counterfeit drug product. When the consumer, physician-prescriber or the interested party is in possession of evidence to prove that the product is counterfeit, he/she shall instead file an affidavit of complaint.</td>
<td>Complainant, LIC, Accredited Complaint Desk</td>
</tr>
</tbody>
</table>

*BFAD is now the Food and Drug Administration per RA 9711.

The complaint may be in the form of a complaint affidavit or a letter of complaint or information:

1. A *Complaint Affidavit from a Drug Establishment or Registered Brand Owner*, which shall be accompanied by samples of counterfeit drug products duly marked for identification purposes, must contain the following information:
   a. name of the product, the lot numbers and expiry date of the products he shall allege as counterfeit;
   b. name and address of the person and/or drug establishment or company he shall name as party-respondent;
   c. specific acts that he shall allege as having been committed by the party-respondent;
   d. remedy or relief or action he shall intend BFAD to take.

2. A *Complaint Letter* has to have the following information:
   a. the name of the suspected product;
   b. the source or the name and address of the person from whom he/she acquired the said suspected drug product;
   c. the mode of his acquisition; and
   d. the reason or fact giving rise to the suspicion that the drug product is counterfeit.

3. An *Affidavit of Complaint* from a consumer, physician-prescriber or interested party shall contain the following information:
   a. the name and address of the person who has committed the act of violation of RA 8203; and
   b. the specific acts committed.
From the above information, it shows that administrative proceedings could start from regular inspection done by FDRO during the monitoring process, from a complaint letter or an affidavit of complaint from a drug establishment or registered brand owner. The identified complainants were: registered brand owner, consumer, physician and other interested parties. The term, ‘complaint’ implicates that someone has been aggrieved or negatively affected by a counterfeit drug such as a drug company whose product has been counterfeited or a consumer who had purchased a counterfeit product. However, the term, ‘complaint’ would limit active reporting by other stakeholders. The law or its IRR does not provide a reporting process that includes proactive reporting of consumers and individuals who have access to information on suspect counterfeit products. A general reporting system that includes individuals other than ‘complainants’ is more appropriate. A protection program for complainants and informants should be in place to address the fear of reporting.

The process by which FDA will coordinate with the different enforcement agencies was not also described in the law. Section 6 (c) simply states that, “to ensure the effective enforcement of the foregoing, the Bureau may enlist the assistance of the national or local law enforcement agencies.” The identification of specific enforcement agencies with their specific scope of functions was not described in both the law and its IRR. This may have contributed to the enforcement agencies’ varying perception of their functions in the monitoring and control of counterfeit drugs, as either reactive or proactive in scope.

**Outcomes of Implementation**

RA 8203 was enacted in 1996 and is therefore in force for more than 18 years. Once implemented, there should be statistical trends that should reflect the status of reporting, cases resolved or prosecuted, number of public awareness programs held and the number of participants, the number of stakeholders joining the advocacy, and ultimately, the kind, quantity and financial value (in Philippine peso) of SSFFC medicines already confiscated, quarantined, and destroyed. The data should emanate from received reports, regular monitoring, operations conducted with enforcement agencies, and networking with various stakeholders. Unfortunately, at present, consolidated data are not accessible at the FDA Head Office. Data on counterfeit cases and the products involved are available in FDA regional offices. The statistics on cases of counterfeit dangerous drugs, however, are available at the PDEA Compliance Division. The public learns about counterfeit medicines from trimedia reports which can also be easily accessed through the internet. Data on the prevalence and incidence of counterfeit cases are very important in determining the outcomes of the implementation of the law.
**Other Findings**

The law provides an expanded definition of counterfeit drugs when compared to the WHO definition. It included unregistered imported drug products with registered counterpart brands in the Philippines. The case against Roma Drug which engaged in the parallel importation of GSK products with FDA-registered counterpart brands was dismissed after the Supreme Court ruled that its prosecution is no longer warranted under RA 9502 (Cheaper Quality Medicines Act). Said ruling affected the interpretation and application of the law by FDA. The Philippine definition of counterfeit drugs under RA 8203 has been challenged and as a result, FDA no longer invokes RA 8203 but rather applies the rule of RA 3720 and RA 9711 to cases of unregistered pharmaceutical products, including those obtained through parallel importation. Therefore, there is an existing discrepancy in the definition of counterfeit drug in RA 8203 and the policy being implemented by FDA regarding unregistered imported drug products. The latter are no longer considered counterfeit drugs.

**RA 9711 (The Food and Drug Administration Act of 2009)**

RA 9711, as a law defining the overall mandate of FDA and as a higher law supporting RA 8203, needs full implementation if sustainable reporting, monitoring, and containment of counterfeit medicinal products in the country has to happen.

The specific provisions of RA 9711 that should be implemented in terms of SSFFC control are the following:

1. **Full implementation pursuant to Sections 5, 14, 19, Chapter 14, Sections 35-37** which will support the following activities related to SSFFC:
   
   a. **Creation of a unit dedicated to SSFFC**

   Section 37 - The FDA, with the approval of the Secretary, shall create organizational units which are deemed necessary to address emerging concerns and to be abreast with internationally acceptable standards. There shall be created additional plantilla positions to augment the human resource complement of the FDA, subject to existing rules and regulations.

   b. **Reporting by all stakeholders**

   Section 5 - To require all manufacturers, traders, distributors, importers, exporters, wholesalers, retailers, consumers, and non-consumer users of health products to report to the FDA any incident that reasonably indicates that said product has caused or contributed to the death, serious illness or serious injury to a consumer, a patient, or any person.
Section 14- To obtain information from any officer or office of the national or local governments, government agencies and its instrumentalities.

c. Monitoring of health products

Section 5- To strengthen the post market surveillance system in monitoring health products as defined in this Act and incidents of adverse events involving such products.

Section 36- The FDA shall establish field offices in all regions of the country to effectively implement its regulatory functions. The current regional food and drug regulatory officers and regional health physicists in every regional office of the DOH shall now be put under the FDA’s sole control and supervision. The regional field office shall also assume primary jurisdiction in the collection of samples of food, drugs, devices and cosmetics being imported or offered for import at a port of entry other than Manila in his/her assigned region...

d. Enforcement

Section 5 (j)- To issue cease and desist orders *motu proprio* or upon verified complaint for health products, whether or not registered with the FDA...

Section 5 (p)- To maintain bonded warehouses and/or establish the same, whenever necessary or appropriate, as determined by the director-general for confiscated goods in strategic areas of the country especially at major ports of entry.

Section 14 (3)- To issue orders of seizure, to seize and hold in custody any article/articles of food, device, cosmetics, household hazardous substances and health products that is/are adulterated, counterfeited, misbranded or unregistered, or drug, in-vitro diagnostic reagent, biologicals, and vaccine that is/are adulterated or misbranded, when introduced into domestic commerce pending the authorized hearing under Republic Act No. 3720, as amended, Executive Order No. 175 (1987), and Republic Act No. 7394, otherwise known as the Consumers Act of the Philippines.

Section 14 (4)- To call on the assistance of any department, office or agency and deputize members of the Philippine National Police or any law enforcement agency for the effective implementation of this Act.

Section 19- The FDA shall establish a Regulatory Enforcement Unit (REU) for a period not exceeding five (5) years from the effectivity of this Act. It shall be composed of at least five (5) qualified personnel in every region who shall be directly under the control and supervision of the Deputy Director-General for Field Regulatory Operations and shall be administratively supported by the field offices.” This unit has the following functions as quoted:

- Bear arms, wear official uniforms and insignias and shall be classified as law enforcement agents;
- Serve and execute rulings, orders, and decisions of the Director-General of the FDA; and
- Execute and serve search warrants and arrest warrants issued by the courts in connection with violations under this Act and related laws concerning the regulation of health products.
e. Laboratory Testing

Chapter 14, Section 35- The FDA is hereby mandated to improve, upgrade and increase the capability of the agency, to test, calibrate, assay and examine samples of health products. For the purpose of achieving the above mandate, there shall be established at least one (1) testing laboratory each in Luzon, Visayas and Mindanao, which shall have the necessary and appropriate state-of-the-art laboratory equipment and personnel complement.

Chapter 14, Section 35- The testing laboratories may be increased by the Director-General, upon approval of the Secretary. Moreover, the Director-General, upon approval of the Secretary, may call upon other government and private testing laboratories to conduct testing, calibration, assay and examination of samples of health products.

Chapter 14, Section 36- The FDA shall establish field offices in all regions of the country to effectively implement its regulatory functions. The current regional food and drug regulatory officers and regional health physicists in every regional office of the DOH shall now be put under the FDA’s sole control and supervision.

The SSFFC Unit

The full implementation of RA 9711 should include the reorganization of the unit within FDA dedicated to SSFFC/counterfeit medicines. This unit will coordinate all regulatory functions, programs, and activities pertaining to counterfeit medicines including collaboration with various stakeholders. International models of multi-stakeholder collaboration had a similar unit established at the medicines regulatory agency rather than at a non-government external organization. In the regulatory framework presented here (Seiter 2010), the enforcing agency should be at the management level to set the regulatory and policy environment for the partnership and through its decentralized nature, could greatly facilitate implementation of programs and activities nationwide. At the international level, the head of this unit should be the focal point for counterfeit medicines.

The current FDA unit is the focal point for counterfeit medicines and the DOH lead person in the Rapid Alert System. The unit is in charge of receiving reports on suspect counterfeiting cases, and subsequently coordinates with REU and the involved enforcement agency (e.g. PNP, NBI) in the conduct of an operation. The same procedure is being followed at the regional level at the CHD with the FDRO at the lead. The operation is limited by the number of FDA personnel at a specific region, province or town.
Reporting by All Stakeholders

To date, reports on suspect counterfeit medicines come from regular FDA monitoring and from enforcement agencies such as PNP, NBI or BOC. Other sources are the post-marketing surveillance by pharmaceutical companies and the pharmacovigilance program by FDA. The quantitative contribution of each of these sources was not regularly determined. Sometime in 2010, the Bantay Gamot program was introduced in drug outlets to encourage consumer reporting. However, the program did not progress as there was poor response from consumers. Much has to be done to create public awareness of the importance of reporting. In addition, fear of the consequences of reporting needs to be addressed by creating a reporting system which includes protection of an individual from any untoward act or litigation from counterfeiters and unscrupulous businessmen.

Effective monitoring of pharmaceutical products should be able to detect SSFFC products anywhere in the country. The establishment of regional field offices as provided in Section 36 will (1) fortify monitoring, (2) enable better interaction and collaboration of FDA with local stakeholders, and (3) reduce time required for transporting and testing drug samples. Laboratories and bonded warehouses for confiscated goods are important facilities for better handling and processing of SSFFC products. Moreover, the accreditation of other government and private laboratories may expedite testing of health products for analysis.

On enforcement, RA 9711 bestows more enforcement authority to FDA to (1) issue cease and desist orders, (2) maintain bonded warehouses for confiscated goods at strategic areas, including major ports of entry, (3) seize and hold in custody products of questionable quality including SSFFCs, (4) call on assistance of any law enforcement agency, and (5) establish a Regulatory Enforcement Unit (REU), which will execute and serve search warrants and arrest warrants in connection with the agency’s regulatory function. The expansion of FDA’s enforcement capacity is expected to improve investigation and processing of suspect counterfeit cases. The problems identified by police units and other enforcers regarding safety of informants, warehouse congestion, and delay in verification of products would be addressed by the full implementation of RA 9711.
D. Proposed Models of Multi-Stakeholders Collaboration

**WHO Program on Counterfeit Medicines**

In 2006, International Medical Products Anti-Counterfeiting Taskforce (IMPACT) was established, as proposed by the WHO, to address the need for greater international cooperation in combating counterfeit medical products. IMPACT aims to (1) improve collaboration among stakeholders, (2) raise awareness, establish mechanisms for the effective exchange of information and to provide assistance on specific issues, (3) develop technical and administrative tools to support the establishment or strengthening of international, regional and national strategies, and (4) encourage and facilitate coordination among different anti-counterfeiting initiatives. To achieve these goals, IMPACT focuses on five key areas (Figure 12):

*Figure 12. IMPACT’s Five Key Areas*

In 2011, a surveillance and monitoring system was designed to encourage a more systematic reporting method. The electronic Rapid Alert Form is a clear, concise and structured form which contains the minimum amount of information that the WHO can use to conduct an initial risk assessment. Pictures, laboratory results or other relevant documents may also be sent to WHO through this form. Upon sending the form, the sender will be notified by WHO within 72 hours. Upon arrival of the form in the WHO headquarters, the form will be downloaded to the SSFFC database and the Quality and Safety of Medicines Team will receive a notification. An initial risk assessment will be conducted focusing on the threat to public health. The sender will then be contacted for additional information regarding the product to be manually filled in the database by the WHO staff. Detailed analysis will be done by cross searching through the database. Final classification will be done to separate substandard medicines due to manufacturing errors from cases intended to deceive the consumers. The pilot study and training workshop were
participated by ten WHO member countries namely, Cambodia, Croatia, Georgia, Indonesia, Kyrgyzstan, Malaysia, Philippines, Russia, Ukraine and Vietnam. The first SSFFC training workshop was hosted by the Philippine FDA at the WHO Regional Office in Manila. After the pilot study, refinements were made in the form to improve ease of completion, and the database to enable better analysis (WHO, 2013).

According to WHO, strengthening political will and commitment, promulgating appropriate legislation, establishing a national drug regulatory authority, developing standard operating procedures and guidelines for drug inspectors, enforcing drug control laws, empowering the judiciary, fostering partnerships with the pharmaceutical industry, importers, wholesalers, retailers, health professionals, community and consumers, and sharing responsibilities in a national, sub-regional, regional and international levels are important in the fight against the problem of SSFFC medicinal products (WHO, 1999).

Each country has to develop its own national strategy against the problem of SSFFC products. Available resources, technology and infrastructure have to be taken into account during the development and implementation of strategies and plans. All concerned stakeholders must be involved. Government agencies, pharmaceutical companies, drug suppliers, health care providers, consumers, and nongovernmental and international organizations could provide useful ideas and expertise (WHO, 1999).

Single sector approach involving only the government may not work in a more complex problem such as SSFFC proliferation. The policy from which the mandate of the government is founded has its flaws and inadequacies when implemented. The partnership approach is a better alternative in that it could utilize the competencies and qualities of several stakeholders in developing improved strategies to effectively combat the problem. Figure 13 describes the attributes of typical stakeholders in a multi-stakeholder collaboration. Each sector has its own core business, main attributes and unique style in achieving its purpose. Their coming together for a common goal widens the range of competencies, aspirations, and possible strategies in addressing the problem. The following are the documented benefits of collaboration. It can provide: (1) innovative approaches to the challenges of sustainable development, (2) range of mechanisms that encourage sharing of competencies and capacities to achieve common goals, (3) access to more resources by drawing on the full range of technical, human, knowledge, physical and financial resources found in all of the stakeholders, (4) dynamic new networks offering each stakeholder better channels of engagement with the wider community and greater capacity to influence the policy agenda, and (5) greater understanding of the value, values and
attributes of each stakeholder thereby building a more cohesive and more stable society. Ultimately, it is the achievement of the common goal that will sustain the success of collaboration (Tennyson, 2011).

![Diagram of stakeholder attributes](image)

**Figure 13. Attributes of typical stakeholders in a collaborative partnership (Tennyson, 2011)**

Of the different international models of multi-stakeholder collaboration discussed in this study, no single model in toto could be considered applicable to the Philippine setting given the differences in the political, economic, social and cultural settings. Certain attributes were adopted in the development of the collaborative models being proposed based on some important considerations. These considerations are: (1) Feasibility – is it possible in the Philippine setting?, (2) Purpose – Why the need for collaboration? (3) Governance and Accountability – Who will take the lead role? Is it supported by a mandate? What will be the
organizational structure? (4) *Composition* – How are stakeholders chosen? What is the contribution of each stakeholder? (5) *Financing* – what partnership arrangement would provide and ensure resources needed to carry out the strategies to achieve the intended goals? (6) *Measurable Outcomes* – What does the collaboration intend to achieve? Are outcomes measurable? (7) *Communication Lines* – how does communication flow?

The first two models being proposed here are based on the features of several international models discussed in this study. The third model is a modified version of the Coalition for Safe Medicines (CSM) incorporating desirable features of other models reviewed and the considerations previously enumerated. The order of discussion will be: structure and functions, key strategies for capacity-building, resource requirements, and proposed phases of implementation.

1. **Model 1: The SSFFC Council**

*Structure and Functions*

The SSFFC Council is an assembly of stakeholders called together for consultation, deliberation or discussion on various issues and concerns. This is a consultative type of engagement by various stakeholders who are capable of supporting the advocacy of FDA through their own programs and activities. In Figure 10, the Council is represented by two circles, representing the information arm and enforcement arm with the FDA at the center. Each circle has the potential stakeholders which could be tapped as members. The choice of FDA at the helm is based on its identification as the lead agency in RA 8203, (2) it was also similar to the setup of several international models, and (3) it being a regulatory body could facilitate cooperation among government agencies and private stakeholders. Within FDA, it should be the SSFFC unit that will represent the agency in the Council as it is currently the designated single point of contact (SPOC) concerning SSFFCs by DOH. The Enforcement Arm is composed of law enforcement agencies and the local government. The inclusion of the local government would facilitate coordination with FDA on matters regarding sale and distribution of SSFFC products in facilities not regulated by FDA such as retail stores for general merchandise. Based on the US model, members of the Information Arm are responsible for reporting or generating information on suspect SSFFC cases and are also involved in disseminating information to increase awareness of SSFFC among stakeholders and the general public. Representatives of health professional organizations (e.g. Philippine Medical Association, Philippine Pharmacists Association,
Philippine Nursing Association), Consumer organizations (e.g. Consumers Union of the Philippines), Patients organization (Philippine Alliance of Patient Organization), Academe (e.g. Association of Schools, Colleges, Universities), Retailers organization (e.g. Drugstores Association of the Philippines), Pharmaceutical Industry (e.g. Pharmaceutical Healthcare Association of the Philippines, Philippine Chamber of the Pharmaceutical Industry), and Health Facilities Organization (e.g. Government Hospital Group, Private Hospital Association) are potential members of the Information Arm. On the left periphery are the external partners already represented in the Council under the Information Arm. They were included in the organizational structure just to show that the work on SSFFCs goes beyond the Council. Members of the Council are expected to communicate with their respective colleagues to promote awareness and education.

Figure 14. The SSFFC Council

The FDA SSFFC Unit will be responsible for convening the SSFFC Council. It should lead in defining the mission and goals of the Council. It should provide guidance regarding the programs, activities and tasks of the Council members in line with the functions of the unit. It will serve as the depository of information on SSFFCs and the source of information for public education through the Information Arm. It coordinates with law enforcement agencies regarding investigation, verification, and administrative processing of suspected counterfeit cases, as mandated by law. At the right upper quadrant of the structure are the international partners (Interpol, IMPACT) in which FDA is coordinating in terms of capacity-building and reporting, among others. The SSFFC unit is in charge of accrediting complaints desk among pharmaceutical associations as provided by the law. Substandard products must be channeled to the CDRR for proper investigation and sanctions while cases of counterfeit medicines should be coordinated with the Enforcement Arm for proper action.
Each stakeholder, similar to the US model, should have a written partnership agreement with FDA stating their commitment to support anti-SSFFC measures as well as their role in educating the public on SSFFCs.

*Key Strategies for Capacity-building*

Capacity-building should be focused on two groups: Enforcement Arm and Information Arm as they require distinct set of competencies for their specific role in the Council. Capacity-building may be in the form of seminars, workshops, observership, distance learning, among others. The KII respondents particularly from FDA, PDEA, IPO and the enforcers have been through trainings conducted by international partners like Interpol, US IPO and IMPACT. These are technical training in the identification, targeting, and dismantling of counterfeits. FDA personnel were trained in conducting operations and in the modern techniques of identifying counterfeit products. Such training activities are useful for government agencies and enforcers who have specific roles in the administrative, regulatory, technical, and enforcement aspects of the anti-SSFFC work. There should be regular updates on new technology as they are utilized by both counterfeiters and anti-counterfeiters. As for the members of the Information Arm, the public health and economic impact of, and the process by which SSFFC medicinal products enter the supply chain should be included in the training. They should also be oriented on value of SSFFC reporting and the procedure for reporting. This should encourage submission of reports and complaints. Within the Council, there should be coaching/tutorials on methods employed by the different stakeholders in combatting the problem of counterfeit medicinal products. The procurement of new technology to aid monitoring is a helpful step in improving the process. The acquisition or development of an electronic reporting and feedback system, when coupled with public education on SSFFC medicines would certainly improve method of reporting to FDA.

*Resource Requirements*

Running the FDA SSFFC unit will require most of the resources for this model: additional personnel to man the SSFFC unit, office space, communication devices, other forms of information technology to be used for recording, communication and the development of a database solely for SSFFC cases. Standard forms, other documentation and IEC materials are to be produced and distributed to both stakeholders in the Information and Enforcement Arms. Distribution of electronic copies of IEC materials may reduce the cost of reproduction as the other stakeholders may shoulder the hard copy reproduction for distribution to their members, similar to the US model. Budget for training and meetings of FDA personnel should be part of the resources, but can also be alternatively funded by member organizations, external partners...
and donors. Since the setting-up of this model would initially involve amendments to the law, it is expected that expenses will also be incurred during the legislation process (Table 10). Fund should also be secured for Council Meetings held at the FDA Office. The purchase of an electronic reporting and feedback system which should capture reports from all sectors is essential to efficient functioning of the unit. The enduser platform of this system should be accessible, user-friendly, with security features, and could be accessed through the internet. The capacity of SSFFC unit to provide quick feedback could be facilitated by technology and dedicated personnel who should check efficiency of the system.

Table 9. Proposed Phases of Implementation for Model 1

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Lead Agency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td><strong>Regulatory Framework Setting Phase</strong> - Amendment of RA 8203 and its IRR</td>
<td>FDA</td>
</tr>
<tr>
<td></td>
<td>• Implementation of RA 9711</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Reorganization of the SSFFC Unit under FDA</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Convening the SSFFC Council</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Collaboration Setup Phase</strong> - Coordination Meetings between SSFFC Unit and other FDA Offices</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Coordination meetings between FDA and different enforcement agencies comprising Enforcement Arm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Coordination meetings between FDA and the different stakeholders under the Information Arm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Council Meetings to plan programs and activities</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Capacity-building (enforcement and FDA, information group)</td>
<td></td>
</tr>
<tr>
<td>Year 2</td>
<td><strong>Implementation Phase</strong> - implementation of strategies, public education and campaigns</td>
<td>All stakeholders and FDA</td>
</tr>
<tr>
<td></td>
<td>• Development of IEC for the public</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Setting-up of SSFFC database under FDA</td>
<td></td>
</tr>
<tr>
<td>Year 3</td>
<td><strong>Evaluation and Planning Phase</strong> - using measures of outcomes</td>
<td>ALL</td>
</tr>
</tbody>
</table>
2. Model 2: The FDA SSFFC Task Force

Structure and Functions

The second model has resemblance with the first model in that the FDA SSFFC Unit is still the lead unit under the agency. The model though, places greater importance in inter-agency collaboration between the SSFFC Unit and other government agencies which handle the regulatory, enforcement and administrative functions necessary to carry out the mandate of RA 8203. This can be seen in Figure 15 where vertically government agencies are above the SSFFC Task Force. The head of the SSFFC unit will act as the lead stakeholder in the National SSFFC Task Force which will be participated in by various stakeholders whose primary roles and responsibilities are in reporting, monitoring, and education of the public on SSFFC through the programs and activities organized by the Task Force. Likewise, members of the Task Force may be assigned specific tasks such as research and policy development, the output of which could be recommended to FDA for adoption.

Similar to the EU model, the FDA will serve as the clearinghouse of SSFFC information which will be transmitted to the different stakeholders. At the regulatory and enforcement level, SOPs and guidelines of collaboration and coordination should be formulated to smoothen the operation and address the barriers recognized by the enforcement agencies. The task force, on the other hand, should be able to address the issues and barriers addressed by the non-government stakeholders in the KII and formulate programs and activities related to the goals of the task force.

Reports from the stakeholders may be directed to the SSFFC Unit for classification. Those considered counterfeit at that level may be transmitted for proper action to the FDA offices (e.g. laboratory testing) or appropriate enforcement agency (e.g. conduct of raid or seizure of products). Reports may also come from an enforcement agency but directly transmitted to the SSFFC Unit. If there are findings or information that may be relevant for public education or which will improve reporting and monitoring, the SSFFC Unit may include them in the agenda for the National SSFFC Task Force. By clarifying the lines of communication between and among the FDA units, its government and non-government partners, there will be proper treatment of both confidential and public information regarding SSFFC products. This model is illustrated in Figure 15.
Key Strategies for Capacity-building

Knowledge building for both the public and the different stakeholders at the start of collaborative engagement would be essential. This could be provided by experts with extensive experience in teaching the ill consequences of counterfeit medicines. Skills development in technical, coordination, and enforcement skills, evaluation of strategies, and documentation is necessary for regulatory and enforcement personnel involved in monitoring and investigating SSFFC cases. The second level will be for the different members of the taskforce with content of training on: general knowledge on SSFFC medicinal products, its impact on health and the society, ways to prevent purchase and use of SSFFC products, identification and detection of questionable products, and how to report suspect SSFFC products. Learning format may be in the form of seminars, workshops, distance learning, and visits to stakeholders’ facilities where participants learn about various experiences and strategies used for SSFFC cases. The procurement of new technology to aid monitoring is a helpful step in improving the process. The acquisition or development of an electronic reporting and feedback system, when coupled with public education on SSFFC medicines would certainly improve method of reporting to FDA.
Resource Requirements

Similar to Model 1, the SSFFC Unit of FDA should be equipped as an office, with adequate personnel, with communication equipment, internet connection, computers, database and office supplies. There should be adequate space for storage of records and confidential information. There should be budget for training and communication as well as fund for meetings. The agency should also look for funding agencies to fund programs and activities planned by the SSFFC Task Force. The legislation process to amend RA 8203 should be allotted budget as well.

Table 10. Proposed Phases of Implementation for Model 2

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Lead Agency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td>• Regulatory Framework Review Phase - Amendment of RA 8203 and its IRR&lt;br&gt;• Implementation of RA 9711&lt;br&gt;• Reorganization of the SSFFC Unit under FDA&lt;br&gt;• Planning the SSFFC Task Force</td>
<td>FDA</td>
</tr>
<tr>
<td>Year 2</td>
<td>• Coordination Phase - Coordination Meetings between SSFFC Unit and other FDA Offices&lt;br&gt;• Coordination meetings between FDA and different enforcement agencies on SOP formulation&lt;br&gt;• Planning sessions of the SSFFC Task Force on programs and activities&lt;br&gt;• Capacity-building (enforcement and FDA, Task Force members)&lt;br&gt;• Implementation phase - Implementation of strategies and public education and campaigns</td>
<td>All stakeholders and FDA</td>
</tr>
<tr>
<td>Year 3</td>
<td>• Evaluation phase – use of measurable outcomes</td>
<td>FDA, Information Arm</td>
</tr>
</tbody>
</table>

It should be noted that in the two models being proposed, the inclusion of local government in the list of enforcers is necessary since a lot of coordination at the local level is critical to successful FDA-enforcer operation. A regional respondent suggested that for them to contribute to the goal of FDA on counterfeit medicines, there should be better coordination between the local government and regional FDA on anti-counterfeit activities. Among the stakeholders, the inclusion of the government health facilities was deliberate since they are also victimized by unscrupulous suppliers. A local government physician from the National Capitol Region complained that counterfeit medicines were delivered together with legitimate products since the supplier subcontracted part of the shipment from an internet-based supplier. As clinicians, physicians do not have any involvement in the procurement process. However, feedback should be solicited from clinicians regarding the effects of medicines they used on patients. The result should be part of supplier evaluation.
3. Model 3: The Coalition for Safe Medicines (Modified)

![Diagram of the modified organizational structure of the Coalition for Safe Medicines]

*Figure 16. The Modified Organizational Structure of the Coalition for Safe Medicines*

**Structure and Functions**

The structure of the recently launched Coalition for Safe Medicines (CSM) is modified to include the FDA SSFFC Unit in the leadership of the group. This is in line with the findings of this study that the governance of successful multi-stakeholder collaboration specific to SSFFC rests with the regulatory agency. Inasmuch that the coalition was formed for greater good of the people, its operation has to receive funding from the government sector which was mandated by law to be the lead agency against counterfeit medicines. Afterall, it is congruent with its role of protecting the quality and safety of medicines in the market. The FDA leadership will also facilitate inter-agency collaboration, especially with law enforcement agencies. The FDS SSFFC Unit should attend to the day-to-day operation of receiving reports, collection of data on SSFFC cases and coordination with law enforcement agencies in the investigation and operation of suspect SSFFC cases. At the same time, it should liaise with the different stakeholders who have pledged support to the cause against counterfeit medicines. The functions formulated for the Coalition are in line with the functions of other models of collaboration such as public information and advocacy, research and policy development. Some of the topics for research such as incidence and prevalence of counterfeit medicines are actually derived from data which FDA should be collecting on a regular basis and collated to provide statistical trends on a year to year
comparison. Since it is being recommended by this study to amend RA 8203 for the purpose of updating definitions and terms, clarifying procedures and adding necessary provisions such as a general reporting system, then a policy study is in place. All of these activities will require some funding.

The composition of CSM is extensive as it already included the Local Leagues and the consumers group in the loop. The health professional organizations and the pharmaceutical industry were well-represented and certain relevant government offices like the DOH National Center for Health Promotion and the Pharmaceutical Division are included. Representative from government health facilities should be added since counterfeit medicines were also encountered in government hospitals. The academe should also include associations of schools of nursing and medicine, being the professions involved in the medication use pathway.

*Key Strategies for Capacity Building*

Since the objective of the multi-stakeholders collaboration is to address the gaps and weaknesses in the current monitoring, reporting, and containment of SSFFC medicinal products, capacity building must be focused on areas that will require interventions from the Coalition. Lack of knowledge on SSFFC still is a concern and therefore, basic training on what SSFFCs are, their public health and economic impact could be given to stakeholders groups who, in turn will be resource speakers for the public. Guidelines in engaging in anti-counterfeit activities must be developed and proper orientation of all stakeholders should follow. Law enforcers, on one hand, are continuously trained in the conduct of operations, in detection technology and other aspects of enforcement. The procurement of new technology to aid monitoring is a helpful step in improving the process. The acquisition or development of an electronic reporting and feedback system, when coupled with public education on SSFFC medicines would certainly improve method of reporting to FDA.

*Resource Requirements*

The reorganization of FDA SSFFC Unit would require additional human resource, larger office space and furniture, computers, electronic database system, reporting and feedback system, standard forms, and other supplies. Logistics for meetings, funding for research, programs and activities are needed. The policy development and the legislation process must be funded in terms of meeting needs and supplies. Capacity-building activities will also require funding and
so with IEC materials. Regarding funds, they may also be sourced from stakeholders willing to share or donate.

Table 11. Proposed Phases of Implementation for Model 3

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Lead Agency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td>• Regulatory Framework Review Phase - Amendment of RA 8203 and its IRR</td>
<td>FDA</td>
</tr>
<tr>
<td></td>
<td>• Implementation of RA 9711</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Reorganization of the SSFFC Unit under FDA</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• CSM Action Planning</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• <strong>Coordination Phase</strong> - Coordination Meetings between SSFFC Unit and other FDA Offices</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Coordination meetings between FDA and different enforcement agencies on SOP formulation</td>
<td></td>
</tr>
<tr>
<td>Year 2</td>
<td>• Capacity-building (enforcement and FDA, Task Force members)</td>
<td>All stakeholders and FDA</td>
</tr>
<tr>
<td></td>
<td>• <strong>Implementation phase</strong> - Implementation of strategies and public education and campaigns</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• <strong>Evaluation and planning phase</strong> - using measurable outcomes</td>
<td></td>
</tr>
</tbody>
</table>

VI. CONCLUSION

The Philippines has the advantage of having policy and legal framework to support the implementation of stricter measures to control the spread of SSFFC products within the pharmaceutical supply chain. However, the current situation in which these products proliferate in the Philippine market revealed the gaps and weaknesses of the current system.

Review of multi-stakeholder collaboration models existing in other countries, review of the laws related to SSFFC medicinal products, key informant interviews of the various sectors who have a stake in pharmaceuticals had led to the proposal of three models of collaboration which could be considered to address the identified gaps in the current system of handling SSFFCs. Amendments and implementation of existing laws should happen to pave the way for better collaboration. Greater responsibility is placed on non-government stakeholders who are expected to report suspect SSFFC medical products, help monitor the pharmaceutical supply chain, and prevent SSFFC medical products from reaching patients and consumers through proper public education. Together, these stakeholders should work with FDA and enforcers to seek strategies, try and evaluate them and carefully apply those which provide positive and consistent results.
VII. REFERENCES


APPENDICES
APPENDIX A: Letter of Request for KII

August ____, 2015

Name __________________________
Position _______________________
Institution/Agency _______________
Address _________________________

Dear _______________

Greetings!

The College of Pharmacy of the University of the Philippines Manila had embarked on a study to address barriers to effective monitoring, reporting and containment of Spurious / Substandard / Falsely-labelled/ Falsified/ Counterfeit Medical Products.

The objectives of this undertaking are to:

- To create a drug regulatory model involving several organizations, parties, agencies, and others with advocacy on quality and safety of medicines;
- To describe the current state of counterfeit drug regulation in the country;
- To help in developing amended or new policies in counterfeit drug regulation in the country; and
- To help in the creation of counterfeit drug regulation frameworks.

In relation to the above objectives, our team will be conducting key informant interviews from different government agencies, non-government associations, pharmaceutical establishments and professional organizations. We will be interviewing key personnel who are involved in counterfeit monitoring, reporting and containment. In addition, we would also collect relevant documents to provide us a clear picture of the control of counterfeit medical products in the country.

We would like to ask your permission to conduct said interviews during the period, August 1 to 30, 2015. We would appreciate your positive response to this request.

Thank you very much.

Sincerely,

YOLANDA R. ROBLES, RPh, PhD
Professor and Former Dean
UP College of Pharmacy
Principal Investigator

4/F Department of Pharmacy, Valenzuela Hall, University of the Philippines Manila
Taft Avenue, Ermita, Manila 1000
Phone Number: (+632) 526-6115
APPENDIX B: Interview Schedule for Government Agencies

Department of Pharmacy
College of Pharmacy
University of the Philippines Manila

General Questions for Government Offices:

1. What is the mandate of this agency with regards to control of SSFFC drugs in the country? Is there any document that defines your role?
2. What legal/regulatory measures are actually being used in relation to your mandate?
3. What procedures or SOPs are used in relation to your mandate? (Are there SOPs to describe bypass operations? Are there preliminary investigations being conducted? Where are the SSFFC contained? Are there guidelines in determining SSFFC?)
4. What are the barriers that you have identified/encountered?
5. What are the current gaps/weaknesses of current government handling of counterfeit drugs?
6. Provide available statistics on number of cases of counterfeit medicines. Is it mandatory to report any incidents of suspect/detected counterfeit medicines?
7. Provide statistics on inspectors and other officials conducting inspections, sites to be inspected, inspections carried out, etc. in the country.
8. Provide statistics on training initiatives aimed for inspectors, enforcement officials, judiciary, health professionals and supply chain stakeholders on the techniques for identification, detection, documentation, reporting and communication on counterfeit medicine?
9. What are the activities that you have undertaken to improve your capacity in fulfilling your mandate?
10. Describe collaboration with different stakeholders such as manufacturers, wholesalers, retailers etc.
11. Do you have any suggestions to improve control of SSFFC in the Philippines?
APPENDIX C: Interview Schedule for Non-Government Organizations

General Questions for NGOs, Professional Organizations or Companies:

1. Do you have a stake on SSFFC? What is it? Please describe.
2. What is/ are your program/ activities related to SSFFC? (i.e. reporting, monitoring, containment) Please describe the nature and target group.
3. What are the barriers that you have identified/encountered?
4. In your opinion, what are the current gaps/weaknesses of current government handling of counterfeit drugs?
5. Do you do reporting of any incident of suspected/ detected counterfeit medicines by various stakeholders? Is there a formal reporting mechanism?
6. Do you have any suggestions to improve control of SSFFC in the Philippines?
APPENDIX D: Health Policy Note 1

Amend the Special Law on Counterfeit Drugs (R.A. 8203) to Widen and Sustain Effective Monitoring, Reporting and Containment of Spurious/Substandard/ Falsely-labelled/ Falsified/Counterfeit (SSFFC) Medical Products

Medicines are made available in all health care systems to address the health problems of the population. It is expected that they conform to national and international standards of quality, efficacy and safety. These attributes have to be maintained at all points of the pharmaceutical supply chain up to the point of care to achieve positive health outcomes. When SSFFC pharmaceutical products enter the commercial market, they brought in health, political and economic burden. While the proliferation of SSFFC is a known complex and global issue that transcends national boundaries, it is expected that governments have the capacity to provide technical and regulatory measures to control the entry and distribution of these questionable medicinal products.

Measurable outputs that characterize effective regulation in a country include: (1) high and consistent quality of drugs in circulation, (2) absence of an informal drug market with unlicensed sellers and drug peddlers, (3) absence of counterfeit, nonregistered and substandard drugs from the market, and (4) documented ability to track side effects and recall unsafe drugs (Seiter 2010). With evidences that questionable drug products still exist in the Philippines, it is clear that there are gaps and weaknesses in the current regulatory system governing SSFFC medicinal products.


The conduct of key informant interviews and review of the provisions of R.A. 8203 and its IRR provided a means to identify gaps between the law and its implementation. The law was able to
provide the procedure for monitoring regulated facilities visited by the FDROs and how to collect samples of suspected counterfeit products.

With the enactment of RA 9711 in 2009 and the subsequent reorganization of BFAD into FDA, there were major changes in the names, functions and scope of responsibilities of the offices and units under BFAD. It followed that the offices mentioned in the law as shown in the procedure for monitoring counterfeit drugs no longer exist (Table 6). The previous functions on counterfeit drugs, however, were assumed by current offices and units. This discrepancy need to be addressed by amendment to RA 8203.

The Special Law on Counterfeit Medicines and its IRR did not identify a specific implementing unit under FDA. At present, this role is assumed by a unit under the Center for Drug Regulation and Research (CDRR) which also handles the pharmacovigilance program. With limited expertise, manpower and resources provided to this unit, the mission of effectively addressing the SSFFC problem at the national level would be significantly hampered.

Current national statistics of suspect counterfeit cases or those of previous years were not available at the time of the study and it is not known if there is an existing database to record all counterfeit cases in the country. Collection of data was not clear in the provision of the law although it is very important in determining the extent of the problem and the effectiveness of interventions done to address it.

There are provisions of the special law on counterfeit drugs that were clarified under the IRR such as monitoring of counterfeit drugs through regular FDRO inspection, forms of reporting, the administrative proceedings and the sanctions for violation of the law. There are, however, areas which were not addressed by the IRR such as the mechanism of coordination between the Bureau and enforcement agencies. The IRR did not describe the roles of customs, police, and intelligence in the handling of suspected counterfeit cases so much so that there are varying expectations of their roles among the law enforcers. Not all agencies’ engagement with FDA is governed by Memorandum of Agreement. Some enforcers consider their role as reactive only but some suggested that their role should be proactive in the sense that they should perform surveillance of counterfeit products in the community.

Accreditation of complaints desk is another function of BFAD (FDA) mentioned in Rule III, Section 6 of RA 8203. “Upon application by an interested pharmaceutical association, BFAD shall accredit complaint desks that may be established by any pharmaceutical organization or
association. The desk shall receive and refer verifiable letter of complaint or information from any of its members about counterfeit drug products. Any letter of complaint or information referred to BFAD by such complaint desk shall be processed in accordance with Section 2 of Rule IV hereof.” However, based on observation and interaction with officers from the professional and retailers association, they were neither informed nor aware of any information from FDA regarding complaint desks on counterfeit medicines. It is presumed that this aspect of the IRR was not implemented at all. This should have facilitated better reporting of suspect counterfeit medicines.

The law states that administrative proceedings could start from regular inspection done by FDRO during the monitoring process, from a complaint letter or an affidavit of complaint from a drug establishment or registered brand owner. The identified complainants were: registered brand owner, consumer, physician and other interested parties. The term, ‘complaint’ implicates that someone has been aggrieved or negatively affected by a counterfeit drug such as a drug company whose product has been counterfeited or a consumer who had purchased a counterfeit product. However, the term, ‘complaint’ would limit active reporting by other stakeholders. The law or its IRR does not provide a reporting process that includes proactive reporting of consumers and individuals who have access to information on suspect counterfeit products. A general reporting system that includes individuals other than ‘complainants’ is more appropriate. A protection program for complainants and informants should be in place to address the fear of reporting.

Finally, the law provided an expanded definition of counterfeit drugs when compared to the WHO definition. It included unregistered imported drug products with registered counterpart brands in the Philippines. The case against Roma Drug which engaged in the parallel importation of GSK products with FDA-registered counterpart brands was dismissed after the Supreme Court ruled that its prosecution is no longer warranted under RA 9502 (Cheaper Quality Medicines Act). Said ruling affected the interpretation and application of the law by FDA. The Philippine definition of counterfeit drugs under RA 8203 has been challenged and as a result, FDA no longer invokes RA 8203 but rather applies the rule of RA 3720 and RA 9711 to cases of unregistered pharmaceutical products, including those obtained through parallel importation. Therefore, there is an existing discrepancy in the definition of counterfeit drug in RA 8203 and the policy being implemented by FDA regarding unregistered imported drug products. The latter are no longer considered counterfeit drugs.
KEY RECOMMENDATIONS

1. R.A. 8203 and its IRR need to be amended in order to update the definition of counterfeit drugs, other terms and names of offices involved in the implementation of the law. It should identify the Food and Drug Administration (FDA) as the lead agency and the offices in the law be changed to the current offices which should assume the functions accorded by law.

2. A specific office or unit in FDA should be created which will be in charge of the work regarding SSFFC including counterfeit medicines and which has the authority to coordinate with government and non-government entities to pursue enforcement, reporting, monitoring and containment of these questionable products.

3. Gathering, classification, treatment, storage and dissemination of data and other information emanating from reports and those obtained from conduct of operations should be specified in the law since flow of information to and from various stakeholders is vital to the operation and function of the FDA office.

4. There is a need to formalize and define lines of coordination of the enforcement agencies of the government such as the Philippine National Police, National Bureau of Investigation, Bureau of Customs, and the Department of Interior and the Local Government (DILG) in order to level off expected roles and expectations. This would also address the sustainability and proper implementation at the regional and local levels.

5. The provision on the establishment of complaints desks in pharmaceutical associations must be pursued to increase the venue for patients, consumers, individuals and defined entities in the law to lodge their reports and complaints regarding SSFFC. In addition, a hotline specific to SSFFC may be created within FDA under the SSFFC unit with dedicated personnel to regularly gather, classify, and channel received information to the right office for proper action.

6. A wider reporting system should be created other than what the law states (complaints from pharmaceutical industry and affected consumers) to include reports from well-meaning individuals and groups who may be knowledgeable of products and circumstances related to SSFFCs.

7. Protection for the informants of SSFFC should be provided in the law to encourage and allay fear of reporting among consumers, health professionals and the public.
APPENDIX E: Health Policy Note 2

Full Implementation of the Food and Drug Administration Act of 2009 (R.A. 9711) to Support and Sustain Effective Monitoring, Reporting and Containment of Spurious/Substandard/Falsely-labelled/Falsified/Counterfeit (SSFFC) Medical Products

Ensuring quality and safety of medicines in circulation in a country is the main function of the Philippine Food and Drug Administration. As the medicines regulatory authority, its effectiveness can be characterized by the following process-related parameters:

- All pharmaceutical businesses are registered and certified on the basis of legally defined criteria for space, storage conditions, equipment, staffing, training, record keeping, manufacturing process, quality assurance, and so on.
- Predictable and transparent pathways exist for registering a pharmaceutical business and licensing a pharmaceutical product.
- Effective processes are in place for detecting side effects and quality problems and for recalling products from the market.
- Prescription is enforced—pharmacists refuse to sell prescription drugs over the counter.
- Adequate, complete, and understandable information is provided for and with every pharmaceutical product for health professionals and patients.
- Advertising and promotion for pharmaceuticals are truthful and in line with the international marketing code.
- All clinical drug trials are registered and adhere to internationally accepted procedural and ethics standards (Seiter 2010).

The failure of regulatory agencies to implement their mandate, as stated above, is indicated by the following outcomes:

- Inconsistent enforcement of good manufacturing practices (GMPs), good distribution practices, and so on, leading to potential quality problems with drugs that are legally in circulation
- Presence of nonregistered, counterfeit, or substandard drugs in the market
- Presence of substandard manufacturing, wholesale, or retail businesses (drug peddlers) in the pharmaceutical sector
- Delays in licensing of pharmaceutical businesses or drugs, nontransparent processes, and potential for corruption (for example, officials may ask for a bribe to provide a license)
- Nonexistent or insufficient reporting mechanisms for side effects and quality problems, creating an inability to recall a faulty product through the distribution system
- Easy purchase of prescription drugs even without prescription
- No easily accessible source for validated information on drugs for professionals, no translation of prescribing information for imported drugs into local languages, and no package leaflet distributed with drugs dispensed to patients
- No monitoring or sanctions for unethical marketing practices or advertisements with exaggerated claims
Clinical trials performed in violation of standards (for example, without obtaining informed consent from patients) (Seiter 2010).

It is clear from the above analysis of Seiter (2010) that the presence of SSFFC in the market is tied up with the capability of the regulatory agency to perform its functions. Results of the existing review of literature on counterfeit drug products in the country together with the observations and statements of key informants revealed gaps and weakness in the regulatory aspect concerning these products. Some of the weaknesses and barriers brought forward by government agencies and non-government stakeholders:

Summary of weaknesses and barriers from government and non-government stakeholders

R.A. 9711, as a law defining the overall mandate of FDA, needs full implementation if sustainable reporting, monitoring, and containment of counterfeit medicinal products in the country had to happen. The specific provisions that require implementation, and which relate to SSFFC control are the following:

2. Full implementation of R.A. 9711 pursuant to Sections 5, 14, 19, Chapter 14, Sections 35-37 which will support the following activities related to SSFFC:

   a. Creation of a Unit Dedicated to SSFFC

      Section 37 - "The FDA, with the approval of the Secretary, shall create organizational units which are deemed necessary to address emerging concerns and to be abreast with internationally acceptable standards. There shall be created additional plantilla positions to augment the human resource complement of the FDA, subject to existing rules and regulations."

   b. Reporting of all Stakeholders
Section 5- “To require all manufacturers, traders, distributors, importers, exporters, wholesalers, retailers, consumers, and non-consumer users of health products to report to the FDA any incident that reasonably indicates that said product has caused or contributed to the death, serious illness or serious injury to a consumer, a patient, or any person.”

Section 14- “To obtain information from any officer or office of the national or local governments, government agencies and its instrumentalities.”

c. Monitoring of Medicinal Products

Section 5- “To strengthen the post market surveillance system in monitoring health products as defined in this Act and incidents of adverse events involving such products.”

Section 36- “The FDA shall establish field offices in all regions of the country to effectively implement its regulatory functions. The current regional food and drug regulatory officers and regional health physicists in every regional office of the DOH shall now be put under the FDA’s sole control and supervision. The regional field office shall also assume primary jurisdiction in the collection of samples of food, drugs, devices and cosmetics being imported or offered for import at a port of entry other than Manila in his/her assigned region...”

d. Enforcement

Section 5- “To issue cease and desist orders *motu proprio* or upon verified complaint for health products, whether or not registered with the FDA...”

Section 5- “To maintain bonded warehouses and/or establish the same, whenever necessary or appropriate, as determined by the director-general for confiscated goods in strategic areas of the country especially at major ports of entry.”

Section 14- “To issue orders of seizure, to seize and hold in custody any article or articles of food, device, cosmetics, household hazardous substances and health products that is adulterated, counterfeited, misbranded or unregistered, or drug, in-vitro diagnostic reagent, biologicals, and vaccine that is adulterated or misbranded, when introduced into domestic commerce pending the authorized hearing under Republic Act No. 3720, as amended, Executive Order No. 175 (1987), and Republic Act No. 7394, otherwise known as the Consumers Act of the Philippines.”

Section 14- “To call on the assistance of any department, office or agency and deputize members of the Philippine National Police or any law enforcement agency for the effective implementation of this Act.”

Section 19- “The FDA shall establish a Regulatory Enforcement Unit (REU) for a period not exceeding five (5) years from the effectivity of this Act. It shall be composed of at least five (5) qualified personnel in every region who shall be directly under the control and supervision of the Deputy Director-General for
Field Regulatory Operations and shall be administratively supported by the field offices." This unit has the following functions as quoted:

- Bear arms, wear official uniforms and insignias and shall be classified as law enforcement agents;
- Serve and execute rulings, orders, and decisions of the Director-General of the FDA; and
- Execute and serve search warrants and arrest warrants issued by the courts in connection with violations under this Act and related laws concerning the regulation of health products.

e. Laboratory Testing

Chapter 14, Section 35- "The FDA is hereby mandated to improve, upgrade and increase the capability of the agency, to test, calibrate, assay and examine samples of health products. For the purpose of achieving the above mandate, there shall be established at least one (1) testing laboratory each in Luzon, Visayas and Mindanao, which shall have the necessary and appropriate state-of-the-art laboratory equipment and personnel complement."

Chapter 14, Section 35- "The testing laboratories may be increased by the director-general, upon approval of the Secretary. Moreover, the director-general, upon approval of the Secretary, may call upon other government and private testing laboratories to conduct testing, calibration, assay and examination of samples of health products."

Chapter 14, Section 36- "The FDA shall establish field offices in all regions of the country to effectively implement its regulatory functions. The current regional food and drug regulatory officers and regional health physicists in every regional office of the DOH shall now be put under the FDA's sole control and supervision."

The SSFFC Unit

The full implementation of RA 9711 should include the reorganization of the unit within FDA dedicated to SSFFC/counterfeit medicines. This unit will coordinate all regulatory functions, programs, and activities pertaining to counterfeit medicines including collaboration with various stakeholders. International models of multi-stakeholder collaboration had a similar unit established at the medicines regulatory agency rather than at a non-government external organization. In the regulatory framework presented here (Seiter 2010), the enforcing agency should be at the management level to set the regulatory and policy environment for the partnership and through its decentralized nature, could greatly facilitate implementation of programs and activities nationwide. At the international level, the head of this unit should be the focal point for counterfeit medicines.
The current FDA unit is the focal point for counterfeit medicines and the DOH lead person in the Rapid Alert System. The unit is in charge of receiving reports on suspect counterfeiting cases, and subsequently coordinates with REU and the involved enforcement agency (e.g. PNP, NBI) in the conduct of an operation. The same procedure is being followed at the regional level at the CHD with the FDRO at the lead. The operation is limited by the number of FDA personnel at a specific region, province or town.

**Reporting by All Stakeholders**

To date, reports on suspect counterfeit medicines come from regular FDA monitoring and from enforcement agencies such as PNP, NBI or BOC. Other sources are the post-marketing surveillance by pharmaceutical companies and the pharmacovigilance program by FDA. The quantitative contribution of each of these sources was not regularly determined. Sometime in 2010, the *Bantay Gamot* program was introduced in drug outlets to encourage consumer reporting. However, the program did not progress as there was poor response from consumers. Much has to be done to create public awareness of the importance of reporting. In addition, fear of the consequences of reporting needs to be addressed by creating a reporting system which includes protection of an individual from any untoward act or litigation from counterfeiters and unscrupulous businessmen.

Effective monitoring of pharmaceutical products should be able to detect SSFFC products anywhere in the country. The establishment of regional field offices as provided in Section 36 will (1) fortify monitoring, (2) enable better interaction and collaboration of FDA with local stakeholders, and (3) reduce time required for transporting and testing drug samples. Laboratories and bonded warehouses for confiscated goods are important facilities for better handling and processing of SSFFC products. Moreover, the accreditation of other government and private laboratories may expedite testing of health products for analysis.

On enforcement, RA 9711 bestows more enforcement authority to FDA to (1) issue cease and desist orders, (2) maintain bonded warehouses for confiscated goods at strategic areas, including major ports of entry, (3) seize and hold in custody products of questionable quality including SSFFCs, (4) call on assistance of any law enforcement agency, and (5) establish a Regulatory Enforcement Unit (REU), which will execute and serve search warrants and arrest warrants in connection with the agency’s regulatory function. The expansion of FDA’s enforcement capacity is expected to improve investigation and processing of suspect counterfeit cases. The problems identified by police units and other enforcers regarding safety of
informants, warehouse congestion, and delay in verification of products would be addressed by the full implementation of RA 9711.

KEY RECOMMENDATIONS

1. Strengthening the regulatory function of the Philippine Food and Drug Administration over SSFFC products is also dependent on the implementation of the law, R.A. 9711. It is therefore, recommended that efforts be exerted to have this law be fully implemented to enable establishment of specific administrative and coordination processes within the agency itself. Particular attention should be provided for the following:
   a. Through the establishment of a specific office to exercise administrative function and coordination, the current fragmented initiatives and activities in the control of counterfeit medicines may be well-coordinated. Subsequently, it is expected that two-way flow of information from FDA and the stakeholders would improve, resources effectively utilized, and the goals of anti-counterfeit interventions be achieved.
   b. A reporting system for complaints and voluntary reporting of suspected counterfeit medicines from drug establishments, groups and individuals must be in place with the function assigned to the FDA unit on counterfeit medicines. Policy and process for the protection of complainants and volunteers who reported must be part of this reporting system.
   c. The effective transmission of information to and from partner government agencies has to be in place and that the FDA unit should be the depository of all information concerning counterfeit medicines from its regional offices and other government agencies. Periodic statistics and other information relevant to public education must be provided by this unit to monitor the success of various strategies against counterfeit medicines.
   d. While enforcement assistance is provided by the PNP, NBI and Bureau of Customs, there is still room to improve coordination of FDA with them through the local government which has the jurisdiction over local police in the regions, provinces and municipalities of the country. Such coordination will not only enhance enforcement of the law but also promote greater awareness of counterfeit medicines among government agencies and the citizens of the different cities and provinces. Relationship with Department of Justice needs to be defined in terms of cases which are classified as criminal in nature.
e. Regional offices and laboratories are necessary for efficient processing of suspected counterfeit cases. This will address delay in the transmission of information and services necessary in the monitoring, reporting and containment of counterfeit medicinal products.
APPENDIX F: Health Policy Note 3

Adoption of a Multi-stakeholder Collaboration Model to Sustain Effective Monitoring, Reporting and Containment of Spurious/Substandard/ Falsely-labelled/ Falsified/Counterfeit (SSFFC) Medical Products

While the lead role to effectively address the problem and proliferation of SSFFC medicinal products in a country resides with the Food and Drug Administration (FDA), the tasks of monitoring, reporting, and containment would require the cooperation and support of other sectors that could contribute possible solutions to the problem. Verified cases of counterfeit medicines that were brought to media’s attention emanate from different parts of the country and as such, FDA has to extend its reach and collaboration with relevant government agencies and non-government entities at the national level. These stakeholders can provide useful ideas and valuable information that will help in the control of SSFFC proliferation nationwide.

The multi-stakeholder collaborative approach has been explored in various aspects of public policy and management. It brings together government and non-government entities together in collective meetings to engage in consensus-based decision-making (Ansell and Gash 2008). To some extent, it is a response to the limitations and failures of the administrative approach to complex policy issues that require identification of various internal and external factors, involvement of key actors outside of the state, and cooperation from the people directly affected by government decisions and resulting policy implementation.

There were cited benefits of collaboration. One is that it can improve the outcomes of the decision-making process by increasing the availability of information available to decision makers, allowing access to diverse knowledge, expertise and ideas. Second is that by having differing opinions, it can unfold a range of uncertainties and risks before a decision is reached. In so doing, there is the opportunity to weigh the benefits against the risks of any decision. When a unanimous decision cannot be reached, then a chance for an agreement based on majority decision could be an option. Thirdly, collaboration was viewed to improve compliance and implementation. This was attributed not only to better decisions but also to a created sense of ownership and responsibility over a chosen course of action (Donahue and Zeckhauser 2011).

Public health and safety is a shared goal of the government and the people it governs. The prevalent problem of SSFFC medicinal products entering the healthcare system with its negative
impact is an area where multi-stakeholder collaboration could be explored as an effective approach to address the gaps and weakness in the prevailing system.

International Models of Multi-stakeholders Collaboration

There were several country-specific collaboration models reviewed, described and analyzed in this study and out of it, three models were created and proposed that could be applicable to the Philippine situation given its political, economic, social and cultural characteristics. A matrix of attributes of the existing models is used as basis for setting up the features of the proposed models. These considerations are:

1. Presence of a policy or legal framework for counterfeit or SSFFC medicinal products in general;
2. Goals and objectives of collaboration are realistic and achievable and are appropriate to the Philippines needs;
3. Stakeholders are both government and non-government entities;
4. Roles and responsibilities of the stakeholders are described;
5. Activities of the collaboration are described;
6. The organizational structure is related to the set goals and described responsibilities of stakeholders;
7. To some extent, there is evidence of positive outcomes of collaboration;
8. Number of years of existence; and
9. Overall strength and presence of weaknesses that could be addressed or mitigated.

From the models of collaboration reviewed, the U.S. model has strong policy and legal framework. The roles of the network and the various stakeholders were formulated by the Counterfeit Alert Network (CAN) which is already a multi-stakeholder group organized by the U.S. FDA. The agency likewise created an internet-based reporting system called MedWatch which provides information regarding medical products of questionable quality in addition to safety alerts. The website allows consumers to report problems with medical products. CAN allowed members of the network to have initiatives of their own which are all documented and consolidated with with FDA.

Another collaboration model, the European Union has its own policy framework with flexibility in implementation since it is made up of 28 countries with some differences in their political and economic systems. The Drug Regulation Authority (DRA) serves as the hub of two-way information, using proactive and reactive information strategies. This model describes more the
flow of communication depending on the goal. Proactive strategy is directed towards improving public awareness about counterfeit medicines through transmission of information from the taskforce to distribution chain, healthcare professionals, media and general public and patients. Reactive information sharing happens when there are actual counterfeit cases that require the information from the distribution chain to task force who will coordinate with the enforcement group.

An example on how this model works is in the case of the United Kingdom Department of Health, Social Services and Public Safety (DHSSPS) which allows two-way transmission of information. The department had formulated guidelines on internet purchase of medicines for the general public and health professionals. It also has a list of registered online medicine providers. The guidelines and other information are made available to their target recipients and could be accessed through the website, www.dhsspsni.gov.uk. The website provides avenue for reporting from the public and it has contact information on a point person within the Medicine Enforcement Services.

Taiwan is also a very good example of a successful model where there is a clear measurement of outcomes of collaboration. Before collaboration happened, amendment to the policy framework was initiated by the government. There was also strong implementation of the law which resulted in which more violators were convicted. The Cross-departmental Task Force, consists of both government agencies and non-government entities, has clear goals; the responsibilities of the stakeholders are well-defined and the Task Force is led by the Department of Health. The extensive list of stakeholders included vital arms of the government – Ministry of Interior, Department of Justice, National Communications Commission, and Intellectual Property Office. The Taiwan model has a good two-way information system which, in their standard still needs to be improved. The reporting system included a toll-free service phone number and a feedback email.

Alongside the Cross-departmental Task Force, the Taiwan Medical Products Anti-counterfeiting Task Force (TMPACT) was formed, which functions like the WHO IMPACT. It is a non-profit, non-government organization that collaborates with the Department of Health on its fight against counterfeit medicines. It provides education programs, aids in counterfeit drug detection, and develops detection techniques. It regularly sends representatives to global anti-counterfeiting meetings, estimate counterfeit drug value in the market, and foster international collaborations. While it operates independently, it coordinates its activities with the
Department of Health. Taiwan then relies on two arms – the government task force and the non-government task force – in its fight against counterfeiting and counterfeit medicines.

In 2014, the Philippine FDA initiated the convening of various stakeholders to establish the Coalition for Safe Medicines (CSM). The coalition has well-defined functions – public information and advocacy, research and policy development. The coalition's activities in relation to their public information and advocacy are: development of Information, Education and Communication (IEC) materials; utilization of different media including social media to disseminate information; conduct of dialogues with the public through symposia, fora, and other similar activities; engagement of other regulatory and enforcement agencies to align policies and facilitate sharing of relevant information; and engagement of healthcare professionals and health facilities to establish networks for collaborative work.

For their research function, the CSM is expected to carry out research in the following areas: incidence and prevalence of counterfeit medicines in the country; scope and extent of counterfeit medicines proliferation; impact of counterfeit medicines (e.g. economic impact, health-related impact); and efficient and effective networks for collaboration (e.g. development of effective systems of reporting and feedback). The outcomes of research are expected to direct the development of new policies and amendment of existing policies. To add, the research data could also be utilized in IEC materials development.

CSM is composed of representatives from government regulatory and enforcement agencies, local government leagues, and relevant organizations, associations and institutions. The Coalition for Safe Medicines was formally launched during the celebration of the NCWACM last November 23, 2015. The officers were introduced together with the members of the coalition. The functions of CSM are in harmony with the expected functions of multi-stakeholders collaboration models in that the major function is the promotion of greater public awareness and education on counterfeit medicines. The research and policy development are added functions. Research may require some funding for it to be sustained. Given its wide composition involving government and non-government entities, there is a wider reach of stakeholders compared to other country models. The organization, however, does not highlight the leadership status of FDA as mandated by law. The FDA instead will act as the Secretariat and would share in the hosting of meetings and related expenses. The leadership of the CSM is currently held by a non-government representative.
The two proposed models have features mostly from the three international models: U.S.A., E.U. and Taiwan. These models were created based on their applicability to the Philippine setting and their similarity in terms of policy framework. The law on counterfeit medicines did not provide mechanism for multi-stakeholders collaboration. As the current setup in the country is fragmented in terms of activities and coordination, there is need to learn from working models which had considerable success in their years of implementation. In the creation of the models, there was a need to balance idealism with practicality, control with flexibility, and regulation with innovation.

It should be made clear that the two models are created for the purpose of improving the current status of monitoring, reporting and containment of the problem of SSFFC in the country.

The implementation components of the model include:

1. Roles and responsibilities of agencies/institutions involved
2. Key strategies for capacity-building
3. Resource requirements
4. Phases of implementation

**Model 1: The SSFFC Council**

*Structure and Functions*

The SSFFC Council is an assembly of stakeholders called together for consultation, deliberation or discussion on various issues and concerns. This is a consultative type of engagement by various stakeholders who are capable of supporting the advocacy of FDA through their own programs and activities. In Figure 10, the Council is represented by two circles, representing the information arm and enforcement arm with the FDA at the center. Each circle has the potential stakeholders which could be tapped as members. The choice of FDA at the helm is based on its identification as the lead agency in RA 8203, (2) it was also similar to the setup of several international models, and (3) it being a regulatory body could facilitate cooperation among government agencies and private stakeholders. Within FDA, it should be the SSFFC unit that will represent the agency in the Council as it is currently the designated single point of contact (SPOC) concerning SSFFCs by DOH. The Enforcement Arm is composed of law enforcement agencies and the local government. The inclusion of the local government would facilitate coordination with FDA on matters regarding sale and distribution of SSFFC products in facilities not regulated by FDA such as retail stores for general merchandise. Based on the US model,
members of the Information Arm are responsible for reporting or generating information on suspect SSFFC cases and are also involved in disseminating information to increase awareness of SSFFC among stakeholders and the general public. Representatives of health professional organizations (e.g. Philippine Medical Association, Philippine Pharmacists Association, Philippine Nursing Association), Consumer organizations (e.g. Consumers Union of the Philippines), Patients organization (Philippine Alliance of Patient Organization), Academe (e.g. Association of Schools, Colleges, Universities), Retailers organization (e.g. Drugstores Association of the Philippines), Pharmaceutical Industry (e.g. Pharmaceutical Healthcare Association of the Philippines, Philippine Chamber of the Pharmaceutical Industry), and Health Facilities Organization (e.g. Government Hospital Group, Private Hospital Association) are potential members of the Information Arm. On the left periphery are the external partners already represented in the Council under the Information Arm. They were included in the organizational structure just to show that the work on SSFFCs goes beyond the Council. Members of the Council are expected to communicate with their respective colleagues to promote awareness and education.

There is a two-way flow of information to and from the Information arm to the Enforcement arm depending on type of information, as reflected in the EU model. It is the discretion of the SSFFC Council to determine which type of information should be transmitted to the right recipient through the FDA SSFFC unit. The unit could meet with either arm (Information or Enforcement) depending on the issue, activity or program at hand. The setup is such that flow of information is consistently facilitated by FDA similar to the EU Task Force’s function.
Each stakeholder, similar to the U.S. model, should have a written agreement with FDA regarding their commitment to support the anti-SSFFC measures espoused by the agency. Initially, a representative of the stakeholder should sit with the SSFFC Council and contribute to the goals and responsibilities of the Council. In addition, the representative has the task of informing members of his organization, institution, and the general public of transmitted information specific to increasing awareness of, and vigilance regarding SSFFC schemes and products.

**Key Strategies for Capacity-building**

Capacity-building should be undertaken by two groups: government agencies as a group and the other, non-government stakeholders. The KII respondents particularly from FDA, PDEA, IPO and the enforcers have been through trainings conducted by international partners like Interpol, U.S. IPO and IMPACT. Their trainings are mostly on knowledge and skills in the identification, targeting, and dismantling of counterfeits. FDA personnel were trained in conducting operations and in the modern techniques of identifying counterfeit products. Such training activities are useful for government agencies and enforcers who have specific roles in the administrative, regulatory, technical, and enforcement aspect of the anti-SSFFC work. There should be regular updates on new technology which are both utilized by counterfeiters and anti-counterfeiters alike. As for the majority of stakeholders, a less technical training is required and should be focused on public health impact and the prevention of the entry of SSFFC medicinal products into the pharmaceutical supply chain from the importation of raw materials, production, distribution, wholesale and retail, procurement and use at health facilities. A second area where capacity-building is needed is on the two-way reporting system for the stakeholders and FDA. A reporting system in addition to the reporting of complaints as described in R.A. 8203 should be developed and used in training of stakeholders who are more involved in generating information on suspect SSFFC cases and who will also be involved in the education of various groups and the public.

**Resource Requirements**

The FDA needs to invest in additional human resources to man the SSFFC unit, office space, communication devices, other forms of information technology to be used for recording, communication and the development of a database solely for SSFFC cases. Standard forms, other documentation and IEC materials are to be produced and distributed to both stakeholders in the information and enforcement arms. Distribution of electronic copies of IEC materials may reduce the cost of reproduction as the other stakeholders may shoulder the hard copy
reproduction for distribution to their members, similar to the U.S. model. Budget for training and meetings should be part of the resources. The development of collaboration may follow the following timeline:

**Proposed Phases of Implementation**

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Lead Agency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td><strong>Regulatory Framework Setting Phase</strong> - Amendment of RA 8203 and its IRR</td>
<td>FDA</td>
</tr>
<tr>
<td>Year 1</td>
<td>• Implementation of RA 9711</td>
<td></td>
</tr>
<tr>
<td>Year 1</td>
<td>• Reorganization of the SSFFC Unit under FDA</td>
<td></td>
</tr>
<tr>
<td>Year 1</td>
<td>• Convening the SSFFC Council</td>
<td></td>
</tr>
<tr>
<td>Year 1</td>
<td>• <strong>Collaboration Setup Phase</strong> - Coordination Meetings between SSFFC Unit and other FDA Offices</td>
<td></td>
</tr>
<tr>
<td>Year 1</td>
<td>• Coordination meetings between FDA and different enforcement agencies comprising Enforcement Arm</td>
<td></td>
</tr>
<tr>
<td>Year 1</td>
<td>• Coordination meetings between FDA and the different stakeholders under the Information Arm</td>
<td></td>
</tr>
<tr>
<td>Year 1</td>
<td>• Council Meetings to plan programs and activities</td>
<td></td>
</tr>
<tr>
<td>Year 1</td>
<td>• Capacity-building (enforcement and FDA, information group)</td>
<td></td>
</tr>
<tr>
<td>Year 2</td>
<td><strong>Implementation Phase</strong> - implementation of strategies, public education and campaigns</td>
<td>All stakeholders and FDA</td>
</tr>
<tr>
<td>Year 2</td>
<td>• Development of IEC for the public</td>
<td></td>
</tr>
<tr>
<td>Year 2</td>
<td>• Setting-up of SSFFC database under FDA</td>
<td></td>
</tr>
<tr>
<td>Year 3</td>
<td><strong>Evaluation and Planning Phase</strong> - using measures of outcomes</td>
<td>ALL</td>
</tr>
</tbody>
</table>

**Model 2: The FDA SSFFC Task Force**

**Structure and Functions**

The second model has resemblance with the first model in that the FDA SSFFC Unit is still the lead unit under the agency. The model though, places greater importance in inter-agency collaboration between the SSFFC Unit and other government agencies which handle the regulatory, enforcement and administrative functions necessary to carry out the mandate of RA 8203. This can be seen in Figure 2 where vertically government agencies are above the SSFFC Task Force. The head of the SSFFC unit will act as the lead stakeholder in the National SSFFC Task Force which will be participated in by various stakeholders whose primary roles and responsibilities are in reporting, monitoring, and education of the public on SSFFC through the programs and activities organized by the Task Force. Likewise, members of the Task Force may
be assigned specific tasks such as research and policy development, the output of which could be recommended to FDA for adoption.

Similar to the EU model, the FDA will serve as the clearinghouse of SSFFC information which will be transmitted to the different stakeholders. At the regulatory and enforcement level, SOPs and guidelines of collaboration and coordination should be formulated to smoothen the operation and address the barriers recognized by the enforcement agencies. The task force, on the other hand, should be able to address the issues and barriers addressed by the non-government stakeholders in the KII and formulate programs and activities related to the goals of the task force.

Reports from the stakeholders may be directed to the SSFFC Unit for classification. Those considered counterfeit at that level may be transmitted for proper action to the FDA offices (e.g. laboratory testing) or appropriate enforcement agency (e.g. conduct of raid or seizure of products). Reports may also come from an enforcement agency but directly transmitted to the SSFFC Unit. If there are findings or information that may be relevant for public education or which will improve reporting and monitoring, the SSFFC Unit may include them in the agenda for the National SSFFC Task Force. By clarifying the lines of communication between and among the FDA units, its government and non-government partners, there will be proper treatment of both confidential and public information regarding SSFFC products. This model is illustrated in Figure 2.
Key Strategies for Capacity-building

Knowledge building for both the public and the different stakeholders at the start of collaborative engagement would be essential. This could be provided by experts with extensive experience in teaching the ill consequences of counterfeit medicines. Skills development in technical, coordination, and enforcement skills, evaluation of strategies, and documentation is necessary for regulatory and enforcement personnel involved in monitoring and investigating SSFFC cases. The second level will be for the different members of the taskforce with content of training on: general knowledge on SSFFC medicinal products, its impact on health and the society, ways to prevent purchase and use of SSFFC products, identification and detection of questionable products, and how to report suspect SSFFC products. Learning format may be in the form of seminars, workshops, distance learning, and visits to stakeholders’ facilities where participants learn about various experiences and strategies used for SSFFC cases. The procurement of new technology to aid monitoring is a helpful step in improving the process. The acquisition or development of an electronic reporting and feedback system, when coupled with public education on SSFFC medicines would certainly improve method of reporting to FDA.

Resource Requirements

Similar to Model 1, the SSFFC Unit of FDA should be equipped as an office, with adequate personnel, with communication equipment, internet connection, computers, database and office supplies. There should be adequate space for storage of records and confidential information. There should be budget for training and communication as well as fund for meetings. The agency should also look for funding agencies to fund programs and activities planned by the SSFFC Task Force. The legislation process to amend RA 8203 should be allotted budget as well.

Proposed Phases of Implementation

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Lead Agency</th>
</tr>
</thead>
</table>
| Year 1 | • **Regulatory Framework Review Phase** - Amendment of RA 8203 and its IRR  
• Implementation of RA 9711  
• Reorganization of the SSFFC Unit under FDA  
• Planning the SSFFC Task Force | FDA |
| Year 2 | • **Coordination Phase** - Coordination Meetings between SSFFC Unit and other FDA Offices  
• Coordination meetings between FDA and different enforcement agencies on SOP formulation  
• Planning sessions of the SSFFC Task Force on programs and activities  
• Capacity-building (enforcement and FDA, Task Force members)  
• **Implementation phase** - Implementation of strategies and public education and campaigns | All stakeholders and FDA |
| Year 3 | • **Evaluation phase** - use of measurable outcomes | FDA, Information Arm |
It should be noted that in the two models being proposed, the inclusion of local government in the list of enforcers is necessary since a lot of coordination at the local level is critical to successful FDA-enforcer operation. A regional respondent suggested that for them to contribute to the goal there should be better coordination between the city government and regional FDA on anti-counterfeit activities. Among the stakeholders, the inclusion of the government health facilities was deliberate since they are also victimized by unscrupulous suppliers. A local government physician from the National Capitol Region complained that counterfeit medicines were delivered together with legitimate products since the supplier subcontracted part of the shipment from an internet-based supplier. As clinicians, physicians do not have any involvement in the procurement process. However, feedback should be solicited from clinicians regarding the effects of medicines they used on patients. The result should be part of supplier evaluation.

The suggested timeline of implementation could be modified based on prevailing circumstances among the stakeholders. The limiting factor would be the time allotted for revision of the law and the full implementation of FDA reforms.

**Model 3: Modified Coalition for Safe Medicines**

![Diagram of Modified Coalition for Safe Medicines]

*The Modified Organizational Structure of the Coalition for Safe Medicines*

**Structure and Functions**

The structure of the recently launched Coalition for Safe Medicines (CSM) is modified to include the FDA SSFFC Unit in the leadership of the group. This is in line with the findings of this study that the governance of successful multi-stakeholder collaboration specific to SSFFC rests with
the regulatory agency. Inasmuch that the coalition was formed for greater good of the people, its operation has to receive funding from the government sector which was mandated by law to be the lead agency against counterfeit medicines. Afterall, it is congruent with its role of protecting the quality and safety of medicines in the market. The FDA leadership will also facilitate inter-agency collaboration, especially with law enforcement agencies. The FDS SSFFC Unit should attend to the day-to-day operation of receiving reports, collection of data on SSFFC cases and coordination with law enforcement agencies in the investigation and operation of suspect SSFFC cases. At the same time, it should liaise with the different stakeholders who have pledged support to the cause against counterfeit medicines. The functions formulated for the Coalition are in line with the functions of other models of collaboration such as public information and advocacy, research and policy development. Some of the topics for research such as incidence and prevalence of counterfeit medicines are actually derived from data which FDA should be collecting on a regular basis and collated to provide statistical trends on a year to year comparison. Since it is being recommended by this study to amend RA 8203 for the purpose of updating definitions and terms, clarifying procedures and adding necessary provisions such as a general reporting system, then a policy study is in place. All of these activities will require some funding.

The composition of CSM is extensive as it already included the Local Leagues and the consumers group in the loop. The health professional organizations and the pharmaceutical industry were well-represented and certain relevant government offices like the DOH National Center for Health Promotion and the Pharmaceutical Division are included. Representative from government health facilities should be added since counterfeit medicines were also encountered in government hospitals. The academe should also include associations of schools of nursing and medicine, being the professions involved in the medication use pathway.

*Key Strategies for Capacity Building*

Since the objective of the multi-stakeholders collaboration is to address the gaps and weaknesses in the current monitoring, reporting, and containment of SSFFC medicinal products, capacity building must be focused on areas that will require interventions from the Coalition. Lack of knowledge on SSFFC still is a concern and therefore, basic training on what SSFFCs are, their public health and economic impact could be given to stakeholders groups who, in turn will be resource speakers for the public. Guidelines in engaging in anti-counterfeit activities must be developed and proper orientation of all stakeholders should follow. Law enforcers, on one hand, are continuously trained in the conduct of operations, in detection technology and other aspects
of enforcement. The procurement of new technology to aid monitoring is a helpful step in improving the process. The acquisition or development of an electronic reporting and feedback system, when coupled with public education on SSFFC medicines would certainly improve method of reporting to FDA.

Resource Requirements
The reorganization of FDA SSFFC Unit would require additional human resource, larger office space and furniture, computers, electronic database system, reporting and feedback system, standard forms, and other supplies. Logistics for meetings, funding for research, programs and activities are needed. The policy development and the legislation process must be funded in terms of meeting needs and supplies. Capacity-building activities will also require funding and so with IEC materials. Regarding funds, they may also be sourced from stakeholders willing to share or donate.

Proposed Phases of Implementation

<table>
<thead>
<tr>
<th>Time</th>
<th>Activity</th>
<th>Lead Agency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Year 1</td>
<td>• Regulatory Framework Review Phase - Amendment of RA 8203 and its IRR</td>
<td>FDA</td>
</tr>
<tr>
<td></td>
<td>• Implementation of RA 9711</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Reorganization of the SSFFC Unit under FDA</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• CSM Action Planning</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• <strong>Coordination Phase</strong> - Coordination Meetings between SSFFC Unit and</td>
<td></td>
</tr>
<tr>
<td></td>
<td>other FDA Offices</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Coordination meetings between FDA and different enforcement agencies</td>
<td></td>
</tr>
<tr>
<td></td>
<td>on SOP formulation</td>
<td></td>
</tr>
<tr>
<td>Year 2</td>
<td>• Capacity-building (enforcement and FDA, Task Force members)</td>
<td>All stakeholders and FDA</td>
</tr>
<tr>
<td></td>
<td>• <strong>Implementation phase</strong> - Implementation of strategies and public</td>
<td></td>
</tr>
<tr>
<td></td>
<td>education and campaigns</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• <strong>Evaluation and planning phase</strong> - using measurable outcomes</td>
<td></td>
</tr>
</tbody>
</table>

**KEY RECOMMENDATIONS**

1. The proliferation of SSFFC medicinal products in the Philippine market continues to pose threat to public health and safety. It is necessary to explore adjunct mechanisms whereby regulation of these products could be strengthened and implemented. It becomes imperative to adopt an applicable model of multi-sectoral collaboration which will be led by the Food and Drug Administration.

2. A committee among stakeholders could be formed initially to review R.A. 9803 and formulate amendments suited to the current organizational setup of FDA and one which allows for multi-stakeholders collaboration.
3. A communication system which will ensure two-way flow of information, filter classified data from those for public domain, encourage reporting by the ‘common tao’ without fear of being placed in danger and which is housed at the FDA Central office should be created by the lead agency.

4. The choice of a model of collaboration, as proposed in this work, should be studied carefully on the basis of implementation realities. Of the three, the Coalition for Safe Medicines is already in place and will only require change in the organizational structure in order to ensure government mandate and financial support.