Global Burden/ COVID-19/Multi-sectoral Approach/ Policies and Recommendations to Combat SFMs

Chair:
H.E HOK Kimchong,
Director General for Health, Cambodia
Global burden of Substandard and Falsified Medicines and strategies to combat SFMs

Ms Pernette BOURDILLON ESTEVE, World Health Organization (WHO)
WHO’s work on substandard and falsified medical products
WHO definitions established by the 2017 WHA

- A common global understanding is necessary for coordination action

**SUBSTANDARD**

Also called ‘out of specification’, these are authorized medical products that fail to meet either their quality standards or their specifications, or both. e.g. Manufacturing error, expired or degraded

**FALSIFIED**

Medical products that deliberately/fraudulently misrepresent their identity, composition or source.

**UNREGISTERED / UNLICENSED**

Medical products that have not undergone evaluation and/or approval by the NRRA for the market in which they are marketed/distributed or used, subject to conditions under national or regional regulation and legislation.

Public health and socioeconomic impact study

Literature review of 10 years of publications commissioned by the Member State mechanism

- **Estimations**
  - **10.5%**
    - Observed failure rate on medicines samples in low and middle income countries
  - **US$ 30.5 billion**
    - Estimated spending on SF medicines in LMIC, based on wholesale level sales

- **Impact models**
  - **72,430-169,271 deaths**
    - Caused by SF antibiotics in children under 5 suffering from pneumonia*
  - **31,000 -116,000 deaths**
    - Caused by SF antimalarials in sub-Saharan Africa**
    - US$ 38.5 Million
      - Estimated spending on SF antimalarials in sub-Saharan Africa**

* University of Edinburgh
** London School of Hygiene and Tropical Medicine
Root Causes

Weak Technical Capacity
- Limited awareness
- Poor oversight
- Lack of resources

Constrained Access
- Availability
- Acceptability
- Affordability

Poor Governance
- Poor procurement
- Unethical practices
- Corruption

SF
Leveraging evidence to shape policy

- Regulatory authorities play an essential role in prevention, detection, and response

Member State mechanism on SF medical products

- with participation from all Member States

WHO Secretariat

- Supports Steering Committee work, including the implementation of some prioritized activities
- Organization of meetings

Global surveillance and monitoring system for SF medical products

Global database, focal point network, specialized technical assistance, advocacy, projects and activities, etc.

2019-20 chair

- Americas
- Africa
- Eastern Mediterranean
- Europe
- South-East Asia
- Western Pacific

Regional representation

- 2-3 annual meetings
- Regional rotation of Chair
- Prioritizes list of activities every 2 years

Regional representation

Steering Committee

DATA

POLICY

COUNTRY

OWNERSHIP

ANALYSIS

INFORMATION
UN sustainable development goals

2030 Sustainable development agenda

WHO’s triple billion

Goal 3

Access to medical products

+ 1 billion UHC
+ 1 billion covered in emergencies
+ 1 billion in better health

Access Roadmap
Ensuring safety, quality, efficacy
Equitable access

SF medical product undermine public health investments

+ 1 billion more people enjoying better health and well-being
+ 1 billion more people better protected from health emergencies
+ 1 billion more people benefiting from universal health coverage

UN sustainable development goals
COVID-19 and SFMs

Prof. Paul NEWTON,
University of Oxford, United Kingdom
COVID-19 and Substandard and Falsified Medical Products

Paul Newton

Medicine Quality Research Group, MORU Tropical Health Network & Infectious Diseases Data Observatory, Centre for Tropical Medicine & Global Health, Nuffield Department of Medicine, University of Oxford, UK

Ex-Lao-Oxford-Mahosot Hospital-Wellcome Trust Research Unit, Mahosot Hospital, Vientiane, Lao PDR
The Impact of the COVID-19 pandemic

- Enormous COVID-19-related emergency efforts are underway to find optimal medical products to prevent infection, diagnose, and treat patients.

- Production and supply chains for COVID-19 candidate therapeutics, and for the multitude of other essential medical products, are dramatically impaired by this crisis.

- Supply chains for critical drugs for other diseases are disrupted because of COVID-19 repurposing, regulatory inspections greatly reduced.

- Much of the world has minimal capacity for producing medicines and vaccines, highly dependent on functional trade routes.

- Without advance preparations for quality assurance of diagnostic tests, medicines and vaccines, the world risks a parallel pandemic of substandard and falsified (SF) products.

- Vital interventions are needed globally to ensure access to safe, quality-assured, and efficacious medical products on which the world’s ~7.8 billion people will depend.

- There are warnings from history of medical inequality during times of crisis. During the Great Plague in Europe in the 1660s quackery was rampant and when cinchona bark became the 17th century treatment of malaria it was vastly adulterated. After World War II, penicillin shortages led to massive falsification.
Competition watchdog to monitor price hikes during COVID-19 outbreak as pharmacists report rising cost of drugs

*The Pharmaceutical Journal* | 9 MAR 2020 | By Carolyn Wickware

Man dies, wife in critical condition after ingesting chloroquine phosphate hoping to stave off coronavirus

Published: March 23, 2020 at 11:11 p.m. ET

FOR IMMEDIATE RELEASE
Sunday, March 22, 2020

*Justice Department Files Its First Enforcement Action Against COVID-19 Fraud*

Federal Court Issues Temporary Restraining Order Against Website Offering Fraudulent Coronavirus Vaccine

The Department of Justice announced today that it has taken its first action in federal court to combat fraud related to the coronavirus (COVID-19) pandemic. The enforcement action filed today in Austin against operators of a fraudulent website follows Attorney General William Barr’s recent direction for the department to prioritize the detection, investigation, and prosecution of illegal conduct related to the pandemic.

"The lack of regulatory oversight is one of the reasons why the region is so attractive to criminals in the business of falsifying medicines. And in West Africa it is a big business. The criminals have been keeping the head of the Intellectual Property Rights Unit at the customs service, Mohammed Babandede, and his team busy of late as the pandemic has created the perfect storm for fake medicines to flourish.

"It is really scary," he said, adding that in one week more than 30 million counterfeit tablets had been seized.

He explained that authorities in Nigeria had provided intelligence on a shipment coming into the Cax Island Port in Lagos, the commercial capital.

"Powerful networks"

The consignment included significant amounts of counterfeit dexamethasone — a medicine believed to treat severe COVID-19 symptoms.

"More than 30 million counterfeit tablets shipped from India were seized in one week in Lagos." Mohammed Babandede Nigerian customs official
Medicine Quality surveyor (MQ Surveyor). See: www.iddo.org/mqsurveyor

Summarizes the available curated evidence on the quality of antimalarials, antiretrovirals, anti diabetic s, cardiovascular meds, antibiotics, veterinary medicines, vaccines and TB drugs in the scientific literature. COVID-19 to follow soon. Accompanied by writing reviews of the epidemiology and impact of SF medical products and gaps in the evidence.
Medicine Quality Monitoring Globe (MQM Globe)
See: https://www.iddo.org/mqmglobe/

This new tool summarizes newspaper articles, retrieved from GoogleNews in (English, French, Chinese, Vietnamese & Spanish), that are related to medicine quality and are curated and mapped on a Globe. The principle target users are medicine regulatory authorities and international organisations. As these are journalistic, rather than peer-reviewed scientific, reports, they will intrinsically be less reliable but we aim that they will give early warning of potential problems needing further investigation. We have enhanced it for COVID-19 and issue curated monthly reports on SF medical products for COVID-19, largely based on the Globe.
Medical Product Quality Report – COVID-19 Issues

Issue 3. August 2020

https://www.iddo.org/mq/research/medical-product-quality-reports

Led by Kerlijn van Assche & Céline Caillet

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Number of alerts on the Medicines Quality Monitoring Globe by category and by week
### Number of articles on the Medicines Quality Monitoring Globe linked to substandard or falsified COVID-19 supplies by month

<table>
<thead>
<tr>
<th>Month</th>
<th>Number of articles</th>
</tr>
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<tbody>
<tr>
<td>January</td>
<td>2</td>
</tr>
<tr>
<td>February</td>
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<tr>
<td>March</td>
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<td>47</td>
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<td>June</td>
<td>64</td>
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<tr>
<td>July</td>
<td>42</td>
</tr>
<tr>
<td>August</td>
<td>62</td>
</tr>
</tbody>
</table>
Major risks for COVID-19 medical products

- Vaccine degradation and ineffectiveness if vaccines not held at correct temperature ranges – some will be plus 4 C and others minus 80 C...
- Vaccine falsification prompted by inadequate access
- Vaccine errors of production when multiple factories produce rapidly
- Falsified and substandard therapeutic medicines, fueled by expense and inadequate access
- Falsified and substandard PPE and diagnostic tests
- In ‘physical’ pharmacies and virtual

- But also for all essential medicines because of impairment of production, supply and regulation and severe global economic stress
What should we do?

- Equitable access (e.g. COVAX), and public engagement to explain the logic behind these decisions and the importance of therapy and vaccination

- Joined up data sharing of reports of substandard & falsified medical products, nationally and internationally and action to respond to them

- Optimization of risk-based post-market surveillance for COVID-19 medical products

- Which portable devices are optimal for screening which COVID-19 medicines in supply chains and how can these be integrated into PMS?

- Map producers of key COVID-19 medicines e.g. if there is a shortage of dexamethasone in a country where is the nearest alternative producer?

- Better international producer and supply chain intelligence for key COVID-19 products

- Mapping of essential medicine stockouts, leading to urgent problem solving

- Avoid disruption to production/supply of other vital products e.g. other key vaccines, diagnostic tests

- How to conduct regulatory inspections in our pandemic world with physical distancing

- National medicine regulatory authority mutual recognition for emergency vaccines and medicines

- How to detect and counter inappropriate hoarding that will lead to inequity & stockouts

- Robust and standardized COVID-19 diagnostic accuracy testing schemes with open data sharing

- Regulation of hand sanitizers – many deaths from methanol poisoning

- How can we learn from our collective unpreparedness for future calamities and for more efficient, cost-effective and joined up global regulatory and supply systems?
Medicine Quality Research Group
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With IT and comms staff of IDDO and MORU [Andrew Payne & Alberto Olliaro]
Clark Freifeld, HealthMap
Substandard and Falsified Medicines Situation in business perspective and Key Recommendation

Mr. Daniel LAVERICK,
EuroCham Myanmar Health Advocacy Group
Falsified and Substandard Medicines
Supply Chain Traceability: Something to Care About

Ignoring Supply Chain Traceability is Costly ...

1. Greater stringency, harsher penalties on quality topics
   Increasing scrutiny from authorities globally to ensure patient safety is not put at risk by supply chain practices

2. Margin-eroding inefficiencies in the supply chain
   The pharmaceutical industry loses on average 4.5% of its potential revenue due to supply chain inefficiencies

3. High Impact on patients safety
   One in 10 drugs sold in developing countries is fake or substandard, with an estimated 1 million deaths are attributed to counterfeit drugs globally

4. Increasing number of Pharma crime incidents
   US$2.6B in estimated annual revenue lost due to counterfeit medicines in SEA alone, not to mention impact on patient health
Supply Chain Traceability: Something to Care About

... But Embracing It Could Save Lives

FALSIFIED AND SUBSTANDARD MEDICINES - INTRODUCTION

Supply Chain a key aspect of “brand as a service”

A strong supply chain and visibility on the end to end movement of your product can be a commercial asset for your brand.

55% of retailers surveyed cited “availability” as a key influencing criteria for brand selection and loyalty.

75% of people with high brand trust will commit to a brand even if it is not the cheapest.

91% think it is important to verify if the authenticity of their medicines.

Nielsen Global Retail-Growth Strategies Survey: [https://www.supermarket.co.za/news-article.asp?id=71098&CatTag=1](https://www.supermarket.co.za/news-article.asp?id=71098&CatTag=1)
Supply Chain Traceability: Something to Care About

And protect against patients’ loss of trust due to rise in counterfeits

Loss of trust due to rise in counterfeit controversies
Counterfeit incidents often involve established brands, which hurts brand trust and reputation.

Brand trust affects patients’ loyalty
40% of consumers will stop buying from a brand if it suffers controversy or displays unethical behavior.

Current safety measures are insufficient
Counterfeiters can replicate product packaging and safety seals. Authorities warned that packaging checks are not a sufficient solution for patients.

Need for a better solution to maintain patient trust
58% are not confident of verifying if a medicine is counterfeit or not.

FALSIFIED AND SUBSTANDARD MEDICINES - INTRODUCTION

Anger intensifies over fake vaccine scandal rocking Indonesia

40%

58%

40% of consumers will stop buying from a brand if it suffers controversy or displays unethical behavior.

58% are not confident of verifying if a medicine is counterfeit or not.
Supply Chain Traceability: A Problem of Collaboration

Traceability Hampered by Problems in Information Exchange

**Challenge 1: Lack of information sharing between parties**
- No mechanism of data transfer between parties along the supply chain
- Lack of information communication between parties create entry points for illicit products from outside the system

**Challenge 2: Unable to track a product’s activity along the supply chain**
- Even if information is exchanged, activities are not consistently tagged to product / package identities and so the effectiveness of sharing is limited
- Efforts to optimize the supply chain are limited by the lack of end-to-end information in a system where feedback loops are interconnected

**Challenge 3: Patient does not have access to information about their product**
- Patients have no access to and way to benefit from the information in the supply chain around product movement and provenance

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**FALSIFIED AND SUBSTANDARD MEDICINES - INTRODUCTION**

**Movement of physical product**

**Movement of information**
A potential Solution

**System of Information Sharing**
- Protects Data Ownership
- Allows for Open Adoption
- Ensures Accurate and Truthful Information
- Allows for two-way engagement on safety-related topics
- Allows simple access to critical supply chain info
- Protects Privacy and Confidentiality

**eZTracker Blockchain Network**
- Allows multi-party activity tagging against serials / product identities
- Allows maintenance of multiple serialization methods
- Guards against “theft” of product serial / identity

**eZTracker Digital ID**
- Challenge 1: Lack of information sharing between parties
- Challenge 2: Unable to track a product’s movement along the supply chain

**eZTracker Mobile**
- Challenge 3: Patient does not have access to information about their product

**A Method Of Tagging Activity to Identity**
- Challenge 1: Lack of information sharing between parties
- Challenge 2: Unable to track a product’s movement along the supply chain
- Challenge 3: Patient does not have access to information about their product

**A Way for Patients to Access This Info**
What is required to make this a reality

Clients and customers

- Partner together to fight against counterfeit drugs
- We are strengthening our promise of integrity by offering eZTracker, a new service which is tagged to our products
- With this new tool, utilising Zuellig Pharma’s services will now come with a stamp of authenticity
- In a split second, eZTracker will allow us to identify if products are authentic and if they are counterfeit, where products enter the supply chain and detect cross-border transactions
- Product recalls will be made exponentially faster with a wider reach

Government

- Partner together to fight against counterfeit drugs
- We are taking an active step to combat counterfeit medicine through the use of blockchain
  Counterfeits can now be detected and traced in seconds as compared to weeks
- eZTracker will provide a communications platform for government agencies to raise patient awareness on the ills of counterfeit medicines

Patients

- Counterfeit medicine is harmful to you
- You now have the power to check if the medication you are taking is real
- With every counterfeit product you detect, you are also helping to save lives

Law enforcement

- Partner together to fight against counterfeit drugs
- We are actively detecting counterfeit products, there needs to be a mechanism to pass this information to relevant authorities to take action

FALSIFIED AND SUBSTANDARD MEDICINES - SOLUTION
FALSIFIED AND SUBSTANDARD MEDICINES - COVID

Summary of Possible Partnerships Areas

1. Prevalence & Patient pool assessment
   - Past Vx programs data

2. Engagement with MoH & Govs
   - Engagement with NGOs

3. HCP – Digital engagement
   - eConsultation: eZConsult
   - CME/Medical Information: Docquity

4. Patient Adherence & Support
   - Adherence: MedAdvisor / Reach52
   - Education Support: Sensely
   - Blockchain eZTracker for Vx Programs

5. Payor / Insurance collaboration
   - Self-insured Corporates access
   - Government Channel Coverage access
   - Private Channel Coverage (Strong)

6. CAPACITY CONSTRAINTS
   - Regional DC, Import, W&D, last mile
   - Premium cold chain delivery
   - eZTracker (Blockchain) : Product Integrity and Smart contracts

Targeted distribution & partnerships
- Product/ QA training (MoH / Clinics etc)

FALSIFIED AND SUBSTANDARD MEDICINES - COVID
Substandard and Falsified Medicines
Situation in policy perspective and Key Recommendation

Prof. Kazuko KIMURA,
Kanazawa University, Japan
Substandard and Falsified Medicines Situation: Policy Perspective and Key Recommendations

29-30 September 2020

Professor Kazuko KIMURA, Kanazawa University, Japan
Procedures to detect substandard and falsified medicines

**Purpose**
- Survey: public health
- Intelligent Investigation: guide, order, search, arrest, seizures etc.
- Planning
- Sampling
- Observation

**Further study** ⇒ cause of defects, constituents, interrelations, etc.

**Quality test**
- Authenticity investigation
  - industry
  - Medicine Regulatory Authority (MRA)
- authentic
  - Yes
  - No ⇒ falsified

**Observation**
- Yes
- No

**Sampling**
- Yes
- No

**Planning**
- Yes
- No

**Intelligent Investigation**
- Yes
- No

**Survey: public health**
- Yes
- No

**conformity**
- Yes
- No ⇒ substandard

Kazuko KIMURA, Kanazawa University, Japan
Larger problem of substandards than falsifieds

<table>
<thead>
<tr>
<th>Authenticity</th>
<th>Falsified</th>
<th></th>
<th>Good quality</th>
<th>Total</th>
<th>Predictive Value</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Poor quality</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>10</td>
<td></td>
<td>1</td>
<td>11</td>
<td>90.9%</td>
</tr>
<tr>
<td></td>
<td>224</td>
<td></td>
<td>560</td>
<td>784</td>
<td>71.4%</td>
</tr>
<tr>
<td></td>
<td>234</td>
<td></td>
<td>561</td>
<td>795</td>
<td></td>
</tr>
</tbody>
</table>

Sensitivity: 4.3%  Specificity: 99.8%

1) Pharmacopoeial tests were implemented 2009-2012
2) 'Authenticity pass' includes those without suspicious features even though governments or manufacturers did not reply to questionnaires.

Source: JPMA, international cooperation 2009-2012

Kazuko KIMURA, Kanazawa University, Japan
Detection of Falsified Medicines correlates with Manufacturers' Response Rate

(Asia & Africa in 2003-2015, n=3,918)

Response Rate

Detection of Falsified Medicines correlates with Manufacturers' Response Rate

Kazuko KIMURA, Kanazawa University, Japan

Cooperation with manufacturers and governments is essential for successful detection of falsified medicines.
Falsified Gentamicin injection - concern about resistance -

Small amount of API

Standard GM

A-069

Source: JPMA, international cooperation report 2014, Jamie Endo  Graduation thesis 2016
# The target ingredients of falsified medicine

<table>
<thead>
<tr>
<th>Diethylene Glycol</th>
<th>Glibenclamide</th>
<th>Sildenafil</th>
</tr>
</thead>
<tbody>
<tr>
<td>Panama(2006)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Falsified Pracetamol Cough Syrup</td>
<td>Hong Kong(2007)</td>
<td>USA(2014)</td>
</tr>
<tr>
<td>200 people died including more than 100 children¹</td>
<td>Falsified Sildenafil (Herbal Medicine)</td>
<td>Chinese Herbal Medicine</td>
</tr>
<tr>
<td></td>
<td>10 people were hospitalized including 1 death and another taken to ICU²</td>
<td>1 person was suffering from hepatotoxicity⁹</td>
</tr>
<tr>
<td>China(2008)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Falsified Armillarisin</td>
<td>China(2009)</td>
<td></td>
</tr>
<tr>
<td>12 people died³</td>
<td>Falsified Glibenclamide</td>
<td></td>
</tr>
<tr>
<td></td>
<td>9 people were hospitalized, 2 died⁵,⁶</td>
<td></td>
</tr>
<tr>
<td>Nigeria(2008)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>118 children died⁴</td>
<td>Falsified Cialis</td>
<td>Falsified Tadalafil</td>
</tr>
<tr>
<td></td>
<td>150 people were hospitalized, seven remained comatose and 4 subsequently died⁷</td>
<td>1 person was suffering from severe hypoglycemia⁸</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Japan (Unknown)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Falsified Cialis</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1 person was suffering from severe hypoglycemia⁸</td>
</tr>
</tbody>
</table>


Source: Akimoto et al. Health Labour Scientific Research Grant Report, Japan, 2019
Various imported Viagra® products

11-001-VIA-20-1 (Fake)
11-012-VIA-AUS-4-5 (Authentic)
11-007-VIA-10-2 (Fake)
11-015-VIA-5-4 (Fake)
11-014-VIA-30-1 (Fake)

Kazuko KIMURA, Kanazawa University, Japan

collected by K. Oodaira, May 2011
Popular materials for falsification of sildenafil products

Kazuko KIMURA, Kanazawa University, Japan

** Judged by a manufacturer, very low quality or non-existing content label


IPMA, international cooperation 2010,

* IP = Impurity Profile
  IP-1: authentic Viagra  
  IP-9: unknown source

** Judged by a manufacturer, very low quality or non-existing content label
Substandard varies according to the methods used

Clavulanic acid  Amoxicillin

B017/CB09/S05BAC2

Kazuko KIMURA, Kanazawa University, Japan

Source: JPMA, international cooperation 2010, 2011
Unrecognised deception for enteric coated medicines

Omeprazole Capsules

X-CT & SEM  Sample No.55 (B-040)

A. Whole granules in a capsule (two colors mixed)
B. X-CT of a pale yellow granule (blue arrow)
C. Higher magnification of red square
D. SEM of the granule
E. X-CT of a white granule (orange arrow)
F. Higher magnification of red square
G. SEM of the granule

Source: Tanimoto and JPMA, international cooperation 2010

Kazuko KIMURA, Kanazawa University, Japan
Dispatcher qualifications for internet sales of Viagra® *

<table>
<thead>
<tr>
<th>Country of dispatch</th>
<th>Dispatcher</th>
<th>License</th>
<th>Authenticity</th>
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<tbody>
<tr>
<td>Hong Kong</td>
<td>A</td>
<td>None*¹</td>
<td>no</td>
</tr>
<tr>
<td></td>
<td>B</td>
<td>Wholesaler*¹</td>
<td>yes</td>
</tr>
<tr>
<td>China</td>
<td>C</td>
<td>No response</td>
<td>no</td>
</tr>
<tr>
<td></td>
<td>D</td>
<td>No response</td>
<td></td>
</tr>
<tr>
<td></td>
<td>E</td>
<td>No response</td>
<td></td>
</tr>
<tr>
<td></td>
<td>F</td>
<td>No response</td>
<td></td>
</tr>
<tr>
<td></td>
<td>G</td>
<td>No response</td>
<td></td>
</tr>
<tr>
<td>India</td>
<td>H</td>
<td>Wholesaler*²</td>
<td>yes</td>
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<td>I</td>
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<td>no</td>
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</tr>
<tr>
<td>USA</td>
<td>O</td>
<td>No response</td>
<td>yes</td>
</tr>
</tbody>
</table>

*1: Drug Office, Department of Health, Licensed Drug Dealers
*2: Drugs Control Department, Govt. of NCT Delhi


Kazuko KIMURA, Kanazawa University, Japan
Key Recommendations:

1. For falsified medicines, control frequently used raw materials and alternatives employed to produce falsified medicines and utilize state-of-the-art technology to identify lawbreakers.

2. For manufacturing and exporting countries: Identify and block regulatory loopholes that allow production and distribution of low-quality medicines. For importing and distributing countries: Strengthen pre- and post-marketing quality controls. Policy makers should ensure adequate funding and personnel to fight SF medicines, in cooperation with other countries where necessary.

3. For personal imports through the internet, international cooperation is indispensable. Exporting countries should cooperate to block inappropriate sales by individuals/companies. Importing countries need to develop efficient tools to stop inappropriate imports. Some countries in the region do not allow personal imports via the internet, and this is the strongest measure.
Thank you!!

Kenroku-park in Kanazawa

Kanazawa railway station
Q & A