Asia-Europe Mechanism to combat SFMs

Chair:
Ms Pernette BOURDILLON ESTEVE,
World Health Organisation (WHO)
Sharing 14th AHMM Joint statement to address SFMs

H.E. KUNG Phoak,
Deputy Secretary General of ASEAN
for ASEAN Social Cultural Community (ASCC)
ASEAN Health Sector Cooperation on Combating Substandard and Falsified Medicines

Presented by
H.E. Kung Phoak
Deputy Secretary General of ASEAN for ASEAN Socio-Cultural Community (ASCC)

Asia-Europe Virtual Forum on Combating Substandard and Falsified Medicines (SFM) / 29 – 30 September 2020

Session at 17.15 – 17.30
ASEAN POST 2015 HEALTH DEVELOPMENT AGENDA

Promoting healthy lifestyle
1. Prevention and control of NCDs
2. Reduction of tobacco consumption and harmful use of alcohol
3. Prevention of injuries
4. Promotion of occupational health
5. Promotion of mental health
6. Promotion of healthy and active ageing
7. Promotion of good nutrition and healthy diet

Responding to all hazards and emerging threats
8. Prevention and control of communicable diseases, emerging infectious diseases and neglected tropical diseases
9. Strengthening laboratory capacity
10. Combating antimicrobial resistance (AMR)
11. Environmental health and health impact assessment (HIA)
12. Disaster Health Management

Strengthening health systems and access to care
13. Traditional and Complementary Medicine
14. Health related MDGs (4, 5)
15. Universal health coverage (UHC)
16. Migrants’ health
17. Pharmaceutical development
18. Healthcare financing
19. Human resources development

Ensuring food safety
20. Food safety

Vision: A Healthy, Caring and Sustainable ASEAN Community
Process in Prioritising Combating SFM in ASEAN

- **2016**: Development of AHC 3 Work Programme in 2016 led by Philippines on 7 Health Priorities
- **2017-2020**: Implementation of the Work Programme of AHC3 (18 activities)
- **July 2019**: Consultative Meeting on Combating SFM (led by Cambodia)
- **April 2019**: 14th SOMHD to include Combating SFM as one the priority initiative
- **August 2019**: 14th ASEAN Health Ministers Meeting, Joint Statement with position on combating SFM
- **2017**: Formal Endorsement of the AHC 3 Work Programme, 12th SOMHD, 2017 in Brunei Darussalam
- **2016**: ASEAN Post 2015 Health Development Agenda (2016-2020)
- **2017**: Finalisation of the ASEAN Action Plan for Combating SFM; Inclusion of activities under AHC3 Work Programme (2021-2025)

Revisions based on SOMHD’s guidance
Joint Statement of the 14th ASEAN Health Ministers Meeting_1/2

• Includes the following commitments on combating Substandard and Falsified Medicines:
  • We further reaffirm our commitment to combat substandard and falsified medical products.
  • We support the finalisation of the ASEAN Action Plan developed with the World Health Organization (WHO) in combating substandard and falsified medicines by strengthening national regulatory mechanisms; coordination and collaboration on the sustained implementation on the prevention, detection and response to eliminate substandard and falsified medicines within countries and across the region, among others; and, building and maintaining an efficient robust supply system which will contribute to ensuring that populations within the region especially in remote areas of AMS have access to safe, effective, affordable and quality medicines.
  • We look forward to further exchanges of views and collaboration, as well as pursue and implement concrete actions on substandard and falsified medicines in the wider context of health cooperation within and outside ASEAN.
Joint Statement of the 14th ASEAN Health Ministers Meeting_2/2

- Includes the following commitments on combating Substandard and Falsified Medicines:
  - We further commit to advocate and closely collaborate with relevant partners and stakeholders on this matter as well as to drive the agenda, and seek further collaboration on substandard and falsified medicines at the 13th Asia-Europe Summit (13th ASEM) to be held in 2020 in Phnom Penh, The Kingdom of Cambodia.

- We task the ASEAN Senior Officials on Health Development on the following:
  - Finalise the ASEAN Action Plan to address substandard and falsified medicines, to advocate and closely collaborate with relevant partners and stakeholders including partners in the 13th Asia-Europe Summit 2020 to be hosted by the Kingdom of Cambodia.
Progress: ASEAN Action Plan for Combating Substandard and Falsified Medicines

• Finalisation of the ASEAN Action Plan for Combating Substandard and Falsified Medicines under the purview of the ASEAN Health Cluster 3 on Strengthening Health Systems and Access to Care

• Action Plan includes initiatives aligned with the prevention, detection and response to communicable diseases/emerging infectious diseases:
  • Education and awareness
  • Regulatory Framework and Strengthening
  • Multi-stakeholder Engagement
  • Supply Chain Integrity
  • Border Control
  • Reporting Systems
  • Evidence-based policy and procedures
Progress: ASEAN Action Plan for Combating Substandard and Falsified Medicines

- Inclusion of activities on combating substandard and falsified medicines in the Work Programme of ASEAN Health Cluster 3 on Strengthening Health Systems and Access to Care (2021-2025)

- During the finalization of the activities on combating substandard and falsified medicines and its inclusion in the 2021-2025 Work Programme, cross-cutting concerns with the relevant sectors under the ASEAN Economic Community and ASEAN Political-Security Community Pillars

- Sustained through the leadership of Ministry of Health – Kingdom of Cambodia
Thank you!

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Sharing functions of falsified Medicine Directive of EU

Prof. Patrick DEBOYSER,
Former Representative at the EU delegation in Thailand
Asia-Europe Virtual Forum on
Combatting Substandard and Falsified Medicines
29-30 September 2020
Phnom Penh, Kingdom of Cambodia

EU Action Against
Falsified Medicines
Prof. Patrick Deboyser
EU Action Against Falsified Medicines

2011/62/EU Directive on falsified medicinal products

Safety features
Reinforcing the distribution chain
Internet sales
Active substances

Directive 2011/62/EU on falsified medicinal products
EU Action Against Falsified Medicines

Reinforcing the distribution chain

Compulsory registration
- for all actors in the distribution chain

New/Updated GDP guidelines:
- For medicinal products (November 2013)
- For APIs (March 2015)

EudraGMDP
- EU database of medicinal product distributors

API distributors
- Mandatory registration with NCAs
APIs can only be imported into the EU if:

- Written confirmation on GMP for API; or
- Exporting country is "listed" by the Commission; or
- EU GMP certificate.

New requirements for API manufacturers:

- Registration of EU API manufacturers and importers;
- Audit by manufacturers of medicinal products;
- Inspections by NCAs;
- Legally binding GMP for APIs (based on ICH Q7)
EU Action Against Falsified Medicines

**EU common logo for online pharmacies**
- Since 1 July 2015, a EU common logo identifies all websites legally selling medicinal products in the EU
- Clicking the logo securely redirects to a list of authorized pharmacies in a given MS

**Online pharmacies must be registered**
- By the NCA of the Member State in which they are established

**Awareness campaigns by MS to inform**
- On the risks of buying online
- On the functioning of the common logo
EU Action Against Falsified Medicines

Safety features

Unique identifier (UI)

Code enabling:
- the identification and
- the authentication
  of a given pack.

Anti-tampering device (ATD)

Device allowing the
verification of whether a
pack has been
opened/tampered with.
Delegated Regulation 2016/161

➢ Lays down detailed rules for the safety features appearing on the packaging of medicinal products
➢ Applies since February 2019 in all MS.
➢ Packs on the market before February 2019 can stay on the market until their expiry date
EU Action Against Falsified Medicines

Regulation 2016/161 provides for:

➢ Technical characteristics of the UI
➢ Repositories system for the UI
➢ Verification of the safety features
➢ List of exceptions from bearing/not bearing the safety features

Regulation 2016/161 does not provide for:

➢ Technical options for the anti-tampering device
EU Action Against Falsified Medicines

Scope: principles

➢ Prescription medicines for human use must bear the safety features.
➢ Non-prescription medicines for human use are exempted.

Scope: exceptions

➢ Prescription medicines exempted from the safety features: homeopathics, radiopharmaceuticals, ATMPs, medical gases, certain solutions, contrast media, allergy tests and allergens.
➢ Non-prescription medicines requested to bear the safety features: Omeprazole 20 or 40 mg (reported incidents of falsification)
EU Action Against Falsified Medicines

Safety features

Unique Identifier (UI) : composition

- **Product code:**
  - ISO-compliant (ISO 15459)
  - < 50 characters
  - globally unique
  - issued by ISO-compliant coding agencies

- **Serial number** (max 20 characters; randomized)
- **Batch number**
- **Expiry date**

<table>
<thead>
<tr>
<th>Product code</th>
<th>Serial number</th>
<th>Batch number</th>
<th>Expiry date</th>
</tr>
</thead>
<tbody>
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<td>(01)09876543210982</td>
<td>(21)12345AZRQF1234567890</td>
<td>(10)A1C2E3G4I5</td>
<td>(17)032021</td>
</tr>
</tbody>
</table>
EU Action Against Falsified Medicines

Safety features

Unique Identifier (UI) : properties

- A unique code (UI) on each pack
- The UI is carried by a 2D barcode (Data Matrix ECC200)
EU Action Against Falsified Medicines

Safety features

Unique Identifier (UI) : properties

➢ A unique code (UI) on each pack
➢ The UI is carried by a 2D barcode (Data Matrix ECC200)
➢ In human readable format

Product Identifier
Serial Number
Expiry date
Lot/Batch number
EU Action Against Falsified Medicines

Verification of the safety features (I)

➢ An **end-to-end** verification system – not a full track & trace system

➢ **One end - Manufacturers/MAH:**
  - UIs are printed on packs and uploaded in a secure repositories system.
  - ATDs are applied on packs.

➢ **Other end – Pharmacies/hospitals:**
  - UIs are systematically verified for authenticity and decommissioned at the time of supply to the public.
  - The integrity of the ATD is checked.
Verification of the safety features (II)

- What happens in the middle of the chain?
- Risk-based verification by wholesalers, who verify the safety features when:
  - The product is not directly supplied from a manufacturing or marketing authorisation holder (or a person supplying on their behalf);
  - The product is returned by another wholesale distributor or a pharmacy.
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Verification of the safety features (III)

➢ End-to-end verification system
➢ Risk-based verifications
Member States can exempt certain persons from the obligations to verify/decommission:

- Veterinarians, dentists, opticians, paramedics, nursing homes, etc. (full list in Article 23)
- In this case the verification/decommissioning of the UI is performed by the wholesaler supplying those persons.

Member States cannot exempt pharmacies nor healthcare institutions.
The Repositories system (I - Characteristics)

- **Main tasks:**
  - store the information on the legitimate UIs, and
  - allow the verification/decommissioning of UIs at any point of the supply chain.

- Physically **located** in the European Union.

- Established and managed by **stakeholders**.

- Supervised by **Member States**.
EU Action Against Falsified Medicines

The Repositories system (II - Architecture)

- Architecture: a distributed system

Source: ESM/EMVO
The Repositories system (III - Access)

- The repositories system can be queried by **verified users**, i.e. users whose identity, role and legitimacy has been verified.

- **National competent authorities (NCAs)** can access the repositories system and the information contained therein for:
  - supervising the functioning of the repositories
  - investigating potential incidents of falsification;
  - reimbursement;
  - pharmacovigilance or pharmacoepidemiology.
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Safety features

References

➢ Q&A published by the Commission:

➢ Regulatory requirements: Implementation plans published by EMA and CMDh

CAPs:

NAPs:
One of these medicines is fake. Can you tell which?

Thank You!
Sharing “Medicrime Convention”
by H.E. Mr. Sergey GLAGOLEV,
advisor to the Minister of Health,
Ministry of Health, Russia
Medicrime Convention

September, the 29th, 2020
Moscow-Phnom Penh

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Adviser to the Minister of Health
Russian Federation
Significance of Medicrime Convention-1

- Only dedicated international legal instrument
  - Addresses Public Health through criminal law
  - Counterfeit and similar crimes

- Focus on patient and consumer protection.

- Aimed at prosecution of offences notwithstanding IP rights violation

- Wide scope
  - Medicines, API, Excipients,
  - Medical Devices Accessories, parts & materials

- Other types of healthcare product may be covered by additional protocols
Significance of Medicrime Convention-2

• Promotes cooperation and information exchange, risk communication and trainings

• Committee of the Parties of the MEDICRIME Convention assure expert approach to monitoring of the implementation

• Option of expert support to the Parties from CoE bodies

• Open treaty for non-European states
| **P**rosecuting certain acts |
| Protecting the rights of victims |
| Promoting national and international co-operation |
Falsification of medical products (FMP)

- MEDICRIME Convention was designed partly having in mind public health epidemics and pandemic crisis.

- Current circumstances are ideal for criminals to exploit these weaknesses and shortages in public health systems.
Advice Committee of the Parties on COVID-19 Pandemic

1. States Parties are reminded of their obligations under the Convention

2. WHO guidelines on fighting the pandemic + national health and clinical guidelines respected

3. States will need to work together to disrupt the supply line

4. Staff availability will be needed

5. Prevention of the unauthorised diversion is critical to prevent criminals exploiting shortages
Thank you for your attention!

Mr Sergei GLAGOLEV
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Russian Federation
Chair of the MEDICRIME Committee

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