



CONCEPT NOTE

Asia-Europe Forum on Combatting Substandard and Falsified Medicines (SFMs)

Ministry of Health Cambodia & Asia-Europe Foundation (ASEF)

29-30 September 2020

Virtual Event

1. Background

Substandard and Falsified Medicines (SFMs)

Substandard medicines are defined as medicines that may contain one or more inadequate quantities of active ingredients or may contain harmful components. In contrast, falsified medicines are medicines that deliberately/fraudulently misrepresent their identity, composition, or source. Both substandard and falsified medicines (SFMs) cause critical damages to public health in various dimensions. Individuals who consume SFMs suffer longer as they disrupt the prevention, control, and management of communicable and non-communicable diseases. The prolonged treatment period will increase the costs of healthcare, and treatment failure will generate public distrust in the health system. Likewise, SFMs have serious consequences such as the loss of lives, the increase of antimicrobial resistance (AMR), and the risk of future pandemic.

Access to quality-assured medicines improves health and saves lives, yet one-third of the world's population lacks timely access to these medicines. The World Health Organisation (WHO) estimates that 10.5% of medicines worldwide are substandard or falsified¹. Other literature indicates that the prevalence of poor-quality medicines was 13.6% (95%CI: 11%-16.3%) in low- and middle-income countries (LMICs)². Even though SFMs are more common in low-income countries, it is important to acknowledge that no country remains untouched by this issue. Due to the increase in connectivity supported by the internet, the manufacturing, distribution, and supply of various forms of SFMs have gained increased access to the global marketplace. For example, the Medicines and Healthcare products Regulatory Agency (MHRA) of the United Kingdom seized more than 1 million doses worth over GBP 2 million of SFMs in 2018³. Subsequently, 123 websites have been shut down, and 535 online adverts have been removed. Multiple sources state that 93-96% of active online medical product sellers are illegally operating worldwide, and this is not only a health threat but also imposes privacy and security risks.

SFMs and COVID-19 Pandemic

The current COVID-19 pandemic also highlights the dangers SFMs poses to society. Border closures and lockdowns have interrupted the supply chain of medicines, which affected the production and distribution of medicines, leading to a lack of supply to meet the demand. As a consequence, the market for SFMs has been created to meet the demand⁴. Illegal suppliers are taking advantage of the pandemic to earn more at the expense of the health of the public through SFMs during the pandemic. In Europe, the public has been urged not to purchase medicines from unauthorised websites⁵. According to Interpol, there has been an increase in COVID-19-related criminal activity, and as a result, have seized approximately 4.4 million units of illicit pharmaceuticals around the world⁶. The strategies put in place to fight the COVID-19 pandemic should include measures to combat SFMs in order to protect citizens.

¹ WHO 2017, A study on the public health and socioeconomic impact of substandard and falsified medical products, Geneva

² Ozawa, S., Evans D. R., et al, 2018, Prevalence and estimated economic burden of substandard and falsified medicines in Low and Middle-income countries, JAMA network, PMID:30646106

³ <https://www.pharmaceutical-technology.com/news/uk-crackdown-fake-medicines/>

⁴ <https://www.bbc.com/news/health-52201077>

⁵ <https://www.ema.europa.eu/en/news/covid-19-beware-falsified-medicines-unregistered-websites>

⁶ <https://www.interpol.int/en/News-and-Events/News/2020/Global-operation-sees-a-rise-in-fake-medical-products-related-to-COVID-19>



SFMs in Asia and Europe

In Asia, the Association of Southeast Asian Nations (ASEAN) Member States actively responded to the growing threat of SFMs by strengthening their legal frameworks, enhancing operational capacity and developing new governance mechanisms to deal with this complex and multi-dimensional issue. As a result, the Greater Mekong Subregion Conference on Combatting SFMs was held from 5-6 November 2018 in Phnom Penh, Cambodia, involving the five Mekong countries (Cambodia, Lao PDR, Myanmar, Thailand, Viet Nam), and China, with the support of the Government of France and the International Institute of Research Against Counterfeit Medicines (IRACM). In his speech, Samdech Hun Sen, Prime Minister of the Kingdom of Cambodia, encouraged participating countries to expand this initiative by involving the other ASEAN Member States and the People's Republic of China to elevate this issue of SFMs to global platforms.

In Europe, the European Union (EU) has established the European Medicines Agency (EMA), which is its own decentralised agency. EMA is responsible for the scientific evaluation, supervision, and safety monitoring of medicines in the EU, which contributes to the fight against SFMs. Furthermore, the EU adopted the Falsified Medicines Directive in 2011, which introduced harmonised pan-European safety and control measures. This allows for easier identification of SFMs, and it improves verifications and controls at the borders and within the EU.

Asia-Europe Meeting (ASEM)

During the 14th ASEAN Health Ministers' Meeting (AHMM) in August 2019, discussions revolved around the challenges of SFMs. An excerpt of the Joint Statement of 14th AHMM for Combatting SFMs is below:

*"We further reaffirm our commitment to combat substandard and falsified 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. 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 Meeting (ASEM13)** to be held in 2020 in Phnom Penh, the Kingdom of Cambodia."*

The Asia-Europe Meeting (ASEM) is an inter-regional, inter-governmental process established in 1996 to foster dialogue and cooperation between Asia and Europe. Currently, it comprises 53 ASEM Partners: 30 European and 21 Asian countries, the European Union, and the ASEAN Secretariat. ASEM addresses a wide range of matters including political, economic, financial, social, cultural, and educational issues of common interest based on the spirit of mutual respect, mutual trust, and equal partnership. ASEM has thus far become one of the key global actors, as it shares 60% of the global population, 65% of the global economy, 55% of the global trade, and 75% of the global tourism⁷.

The Asia-Europe Foundation (ASEF)⁸, founded in 1997, is an inter-governmental not-for-profit organisation and is the only institution of ASEM. Following the 6th ASEM Summit (ASEM6; 2006; Helsinki, Finland), where the leaders expressed their determination to combat avian influenza and a possible human influenza pandemic, the ASEM Initiative for the Rapid Containment of Pandemic Influenza, financially supported by the Government of Japan, was approved in principle at the ASEM Senior Officials Meeting (2008, Ljubljana, Slovenia). It was officially launched at the 9th ASEM Foreign Ministers' Meeting (ASEM FMM9; 2009; Hanoi, Viet Nam). Since then, the 2 components of the Initiative (ASEM Stockpiling of Anti-viral Drugs and Personal Protective Equipment, as well as ASEF Public Health Network) have been contributing to strengthening ASEM Partners' capacity to manage public health emergencies.

As Chair of the upcoming 13th ASEM Summit (ASEM13), Cambodia commits to revitalise the efforts and strengthen mutual benefits among ASEM Partners across Asia and Europe, especially in the field of

⁷ ASEM Information Board, "ASEM in Numbers," ASEM Information Board, <https://www.aseminfoboard.org> (access on 13-Nov-19)

⁸ <http://www.ASEF.org>



combatting SFMs. Thus, the Ministry of Health of Cambodia together with the ASEF Public Health Network will host the Asia-Europe Forum on Combatting Substandard and Falsified Medicines, on 29-30 September 2020. The forum will take place virtually due to the current COVID-19 pandemic.

2. Objectives

The main objectives of the forum are to:

- (1) Raise awareness on the dangers that SFMs pose to public health and even beyond the health sector, such as causing economic burdens on the country
- (2) Discuss the impact from the COVID-19 pandemic on SFMs, and develop recommendations to overcome related challenges
- (3) Share the commitment of the ASEAN through the Joint Statement of the 14th AHMM to address SFMs
- (4) Encourage dialogue between Asia and Europe among the stakeholders from diverse sectors for policy implementation and law enforcement on SFMs
- (5) Agree on priorities for multisectoral and/or international cooperation between Asia and Europe on combatting SFMs

The key recommendation will be elevated to the ASEM13, which will be held in Cambodia.

3. Title and Conduction of the Forum

- a. **Title:** “Asia-Europe Forum on Combatting Substandard and Falsified Medicines”
- b. **Venue:** Virtual Event
- c. **Date:** 15:00 to 18:00 (GMT+7) on 29-30 September 2020

4. Organisation of the Forum

- a. **Format of the forum**
Keynote speeches, plenary discussions, and case study presentations from selected countries/organisations.
- b. **Participants:**
 - (1) Officials from ASEM Partners* with the following criteria will be invited:
 - High-level officials of the Ministries of Health (senior official level equivalent to the level of Director General for health, in pharmaceutical or related fields);
 - Heads of the National Regulatory Authority; and
 - High-level officials from non-health sectors such as justice, police, customs, etc.

Delegates from the ASEAN Secretariat (Health Division and Health Standard and Conformance Division), the European Commission’s Directorate-General for Health and Food safety (DG-SANTE), and World Health Organisation (WHO-EURO, WHO-WPRO, WHO-SEARO, and WHO Cambodia Office) will also be invited.

- (2) Representatives from the Council of Ministers, Ministry of Foreign Affairs (MOFA), Ministry of Economic and Finance (MEF), Ministry of Interior (MOI), Ministry of Justice (MOJ), Ministry of Commerce (MOC), Ministry of Information (MOI), Inter-Ministerial Committee for Combatting Counterfeit Medicines, and Provincial Health Departments in Cambodia



- (3) Representatives from non-governmental and private sectors such as pharmaceutical associations, academia, civil societies, trade organisations, the pharmaceutical industry, and chambers of commerce

** The 53 ASEM Partners including; Australia, Austria, Bangladesh, Belgium, Brunei Darussalam, Bulgaria, Cambodia, China, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, India, Indonesia, Ireland, Italy, Japan, Kazakhstan, Korea, Lao PDR, Latvia, Lithuania, Luxembourg, Malaysia, Malta, Mongolia, Myanmar, Netherlands, New Zealand, Norway, Pakistan, Philippines, Poland, Portugal, Romania, Russian Federation, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, Thailand, United Kingdom, Viet Nam, the ASEAN Secretariat and the European Union.*

5. Co-organisers

- (1) Ministry of Health (MOH), the Kingdom of Cambodia
- (2) Asia-Europe Foundation (ASEF)

6. Expected Outputs

- (1) Lessons learnt, best practices and experiences on Combating SFMs in Asia and Europe.
- (2) Identified potential international, inter-regional and multi-sectoral collaboration to intensify the fight against SFMs among the countries and relevant stakeholders across Asia and Europe
- (3) The outcome of this forum to be elevated to the 13th ASEM Summit, which will be hosted in Cambodia 2020.