



# Cambodia Experiences in Addressing Substandard and Falsified Medicines

**Presented by Dr. Or Vandine, PN, MD, MPH.**

*Secretary of State, Spokesperson and Chair of Ad-hoc Committee for Rolling Out COVID-19 Vaccination Throughout the Country (ACC-19),  
Ministry of Health of Cambodia*

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# 1. General Aspects of Medicines:

- The medicines are considered an integral part of the health and social protection system.
- They are an indispensable element for health services delivery and are also a requirement for high-quality of care.
- They are one of the key contributed aspects in addressing the financial risk and social protection strategy to achieve the Universal Health Coverage (UHC).
- The most direct costs of substandard and falsified medicines (SFMs) to households, they spend on medicines that cause harm, or that do not work are contributed to the failure or ineffective health care of the country.

# 1. General Aspects of Medicines – Cont.:

- Around the world, particularly in emerging economies and developing countries, poor quality medicines have a significant impact on the national clinical and economic burden.
- Increasing availability and circulation of deliberately substandard and falsified medicines are also reaching patients because of poor manufacturing and quality-control practices in the production of genuine drugs (either branded or generic) and lack of capacities and collaboration in detection and response to this public health concern.
- A concerted effort is required on the part of governments, drug manufacturers, charities and healthcare providers to ensure that only drugs of acceptable quality reach the patient.



## 2. Definition of SFMs :

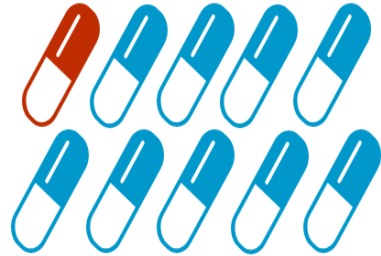
**According to the World Health Organization (WHO), SFMs are defined as the following:**

- ***Substandard medical products:*** also called “out of specification”, these are authorized medical products that fail to meet either their quality standards or their specifications, or both.
- ***Falsified medical products:*** medical products that deliberately / fraudulently misrepresent their identity, composition or source.

### 3. SFMs & Public Health Dangers:

- *Key findings of the public health and socio economic impact study (WHO estimates, 2017) :*

10.5%



Observed failure rate of analysed medical product samples from low and middle-income countries

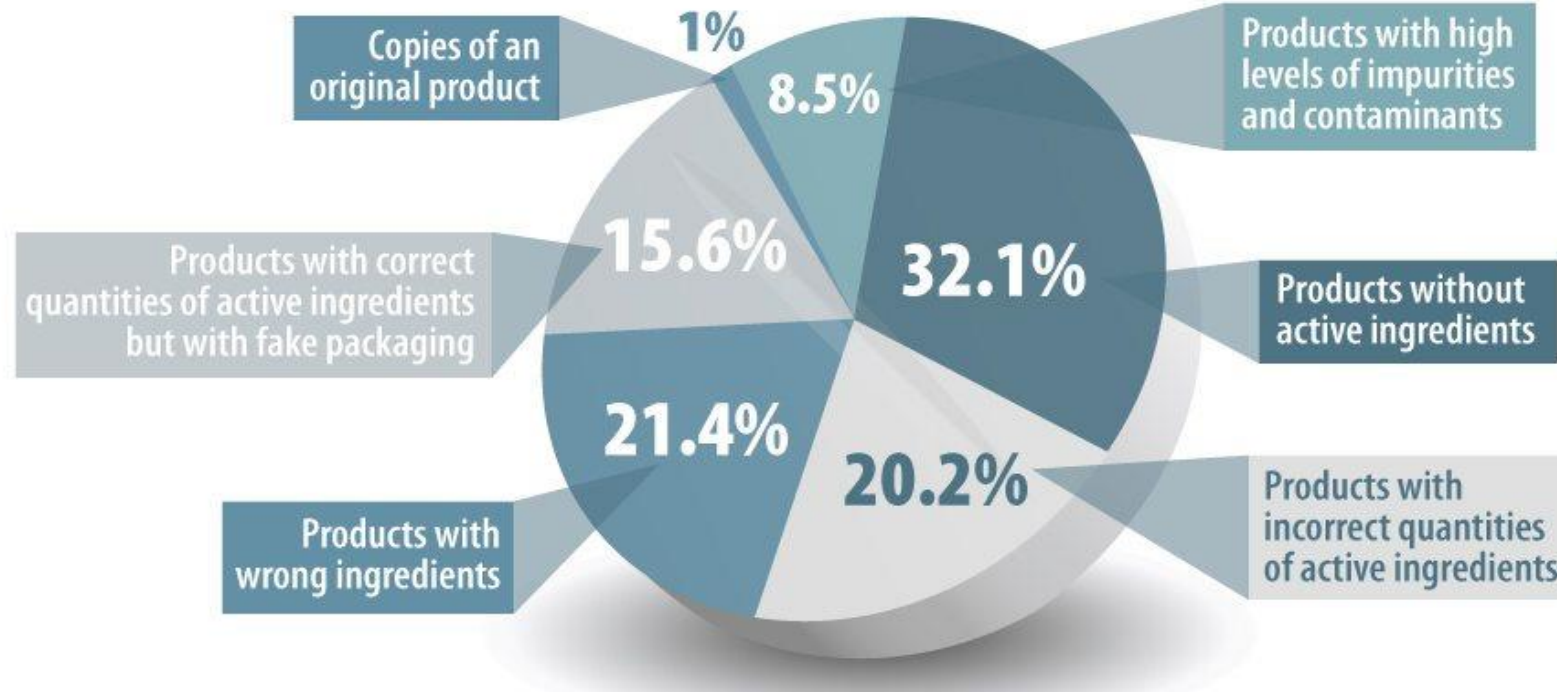


US\$ 30.5  
Billion

**Estimated spending** on SF medical products in low and middle-income countries based on un-weighted estimates of pharmaceutical sales

[www.who.int/medicines/regulation/ssffc/publications/se-study-sf/en](http://www.who.int/medicines/regulation/ssffc/publications/se-study-sf/en)

# 3. SFMs & Public Health Dangers – Cont.:



Source: [nursing school hub](#), *The impact of counterfeit drugs in South and South-East Asia*,  
Published by [Ariel Arcebedo](#) on September 21, 2020

# 3. SFMs & Public Health Dangers – Cont.:

- ❖ Toxic and cause harm to patients and income lost contributing to poverty
- ❖ Affect performance of health, especially wrong impression of care and treatment ability and capacity leading to the failure of treatment
- ❖ Lost of confidence in health care providers and system
- ❖ Weaken country production and development performance particularly serious impact on economy and society
- ❖ Increase disease severity, opportunity for virus or microbe mutations, drug resistance and likelihood of getting more diseases with difficulty in proper diagnosis on time
- ❖ Production & organization of SFMs are an activity of indirect crime globally, regionally, and locally



## 4. Effort & Experiences in Combatting SFMs :

- 1. Regional Conference on Combating SFMs conducted in Phnom Penh, Cambodia on 5 – 6 November 2018** under the wise initiative of & presided over by **Samdech Akka Moha Sena Padei Techo Hun Sen, Prime Minister of the Kingdom of Cambodia**, in collaboration with French Embassy in Phnom Penh, International Institute of Research Against Counterfeit Medicines (IRACM), WHO and other related partners.
- 2. Cambodia as Chair of SOMHD:** inclusion of SPM's initiative in the 14th ASEAN Senior Officials Meeting on Health Development (SOMHD) and Related Meetings.
3. The technical consultative meeting of AMS on **27-28 June 2019** with the technical support by WHO was successfully conducted in Siem Reap, Cambodia.

# 4. Effort & Experiences in Combatting SFMs :

**4. Drafting of agreed action points** was presented to the 14<sup>th</sup> AHMM meeting and related meetings on 29 – 31 August 2019. The 14<sup>th</sup> AHMM Joint Statement was issued with the inclusion of the following points.

- ✓ *To commit to combat substandard and falsified medicines.*
- ✓ *To support the finalization of the ASEAN Action Plan developed with WHO's support in combating SFMs by strengthening national regulatory mechanisms; coordination and collaboration on the sustained implementation on the prevention, detection, and response to eliminate SFMs 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.*
- ✓ *ASEAN Action Plan for Combating SFMs was incorporated into ASEAN Health Cluster 3 Work Programme from 2021 to 2025 which was endorsed by AHC3 on the draft version 6 of the AHC3 work program 2021-2025 on 29<sup>th</sup> April 2022. This draft was adopted on 14 May 2022 at the 15<sup>th</sup> AHMM meeting.*

## 4. Effort & Experiences in Combatting SFMs – Cont.:

**5. The Asia-Europe Forum on Combating SFMs:** was virtually organized successfully on 29-30 September 2020 by the Ministry of Health of Cambodia in collaboration with the Asia-Europe Foundation (ASEF). The objectives and outputs of the forum were below:

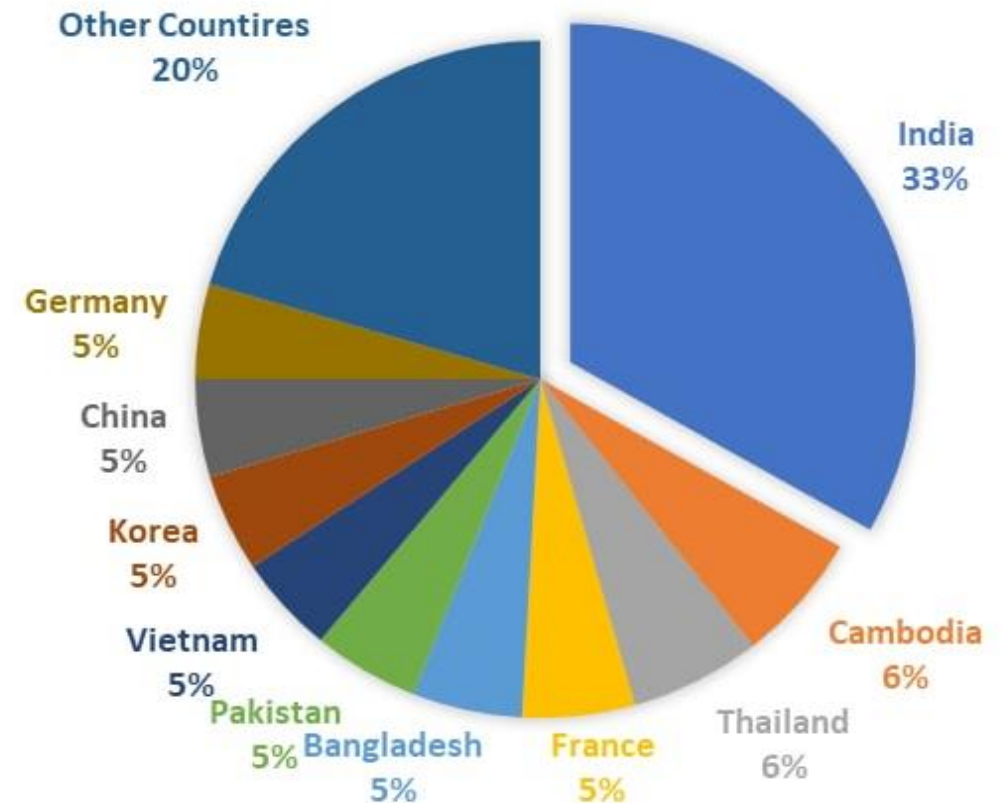
- *Raise awareness of the dangers that SFMs pose to public health and even beyond the health sector, such as causing economic burdens on the country*
- *Encourage dialogue between Asia and Europe among the stakeholders from diverse sectors for policy implementation and law enforcement on SFMs*
- *Agree on priorities for multisectoral and/or international cooperation between Asia and Europe on combatting SFMs.*
- *Propose Key Recommendations to work collaboratively between Asia and Europe as well as relevant stakeholders to prevent, detect, and respond to this issue.*

# 4. Effort & Experiences in Combatting SFMs – Cont.:

## 6. Current Status drug outlets in Cambodia (as of July 2022):

• Manufacturers for pharmaceutical	14
• Manufacturers for medical devices	17
• Import-export company for pharmaceutical	593
• Pharmacy	2708
• Depot A	329
• Depot B	293

## 7. Current Status of Medical Products registered in Cambodia ( 28,401 products as of 30 Dec 2021):



# 4. Effort & Experiences in Combatting SFMs – Cont.:

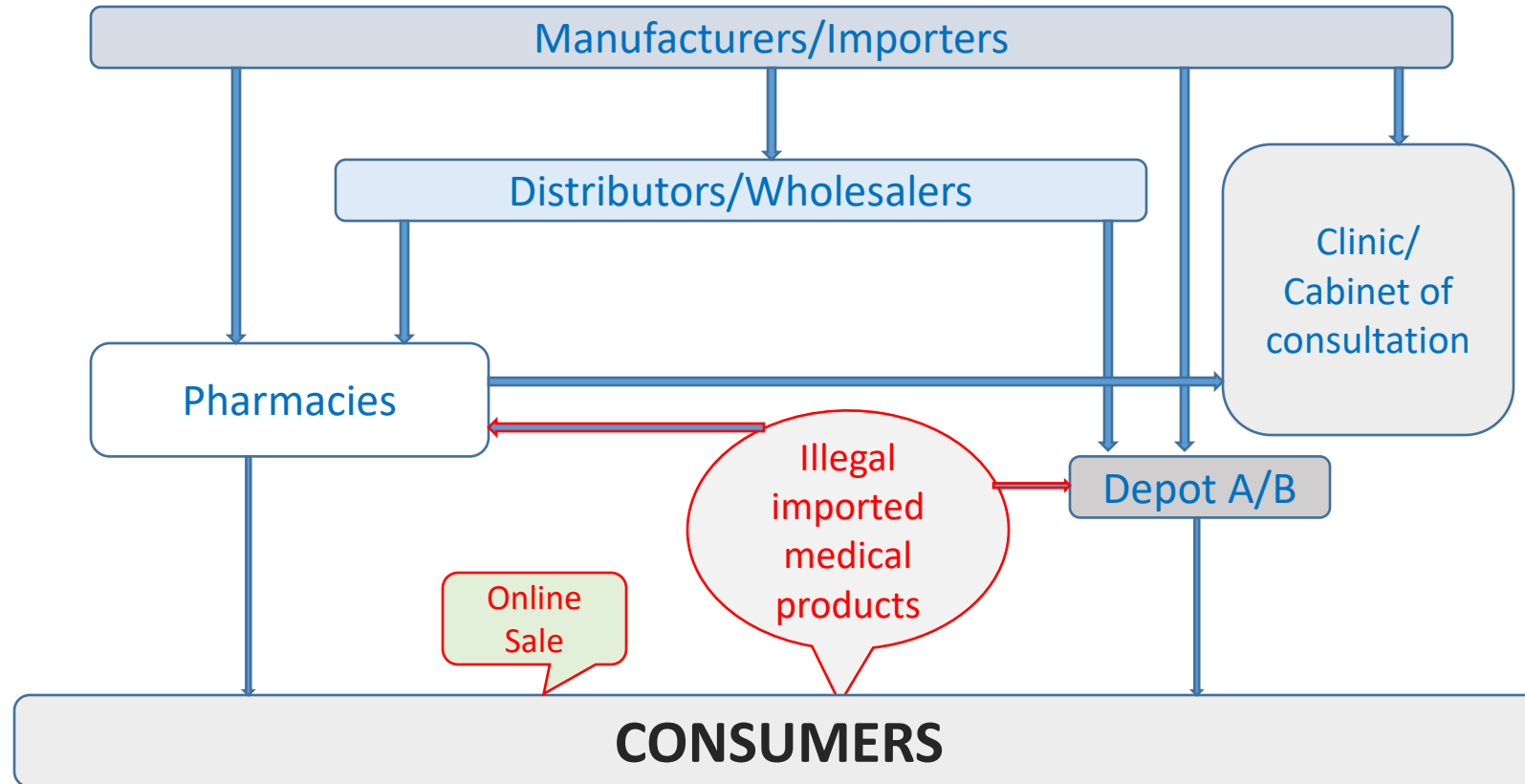
## 8. COVID-19 Therapies, COVID-19 Vaccines and Rapid Test for SARS-CoV-2 Antigen Test :

- ❖ Approval Procedure: Utilisation of regulatory reliance (WHO-EUL, TGA, and MoH Prakas on fast-track registration)
- ❖ COVID-19 Therapies and Rapid Test approval:
  - Molnupiravir : 09
  - Remdesivir : 01
  - Favipiravir : 04
  - COVID-19 Vaccines : 17
  - Rapid Test for SARS-CoV-2 Antigen Test : 41



# 4. Effort & Experiences in Combatting SFMs – Cont.:

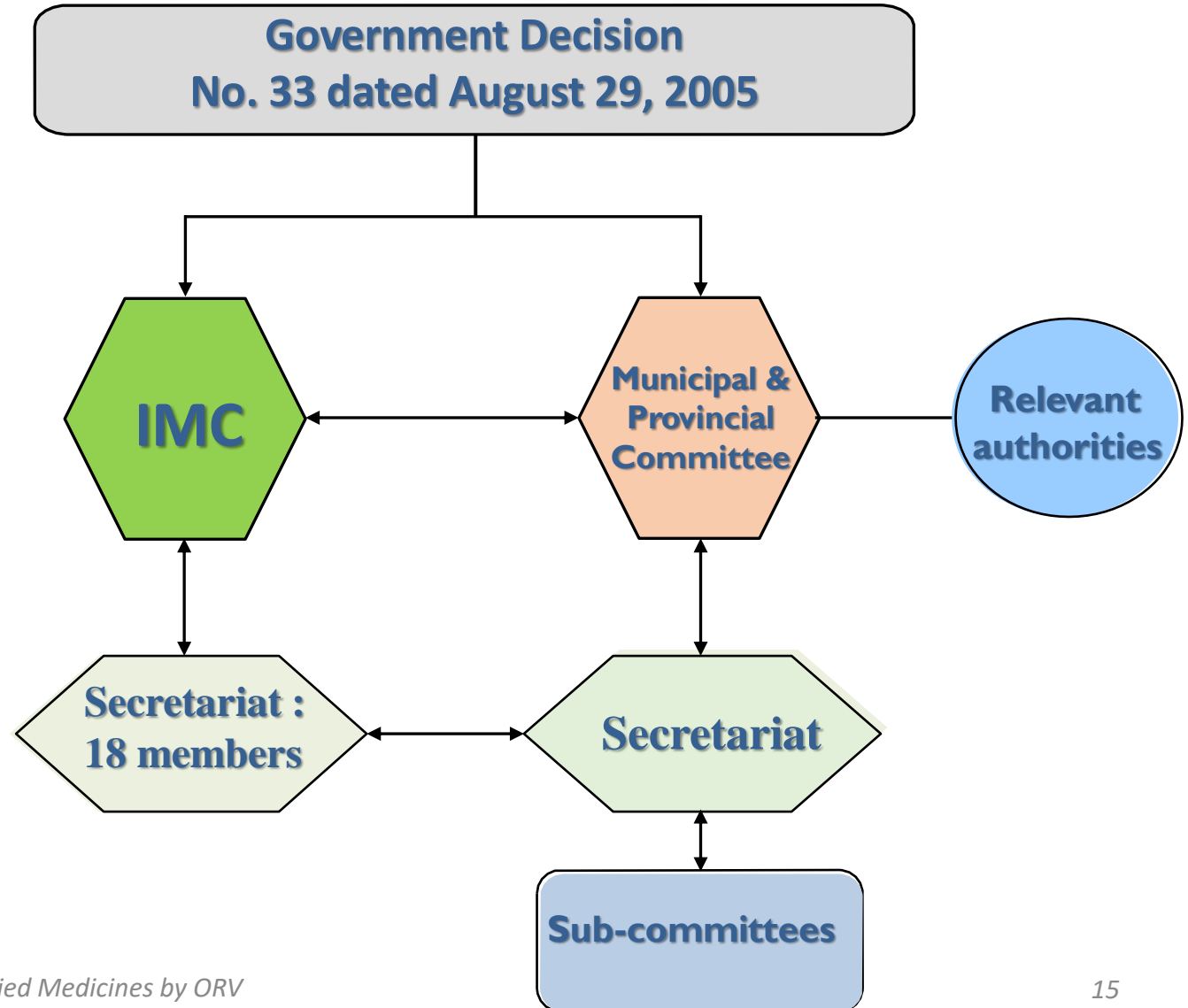
## 8. How SFMs enter into circulation?



# 4. Effort & Experiences in Combatting SFMs – Cont.:

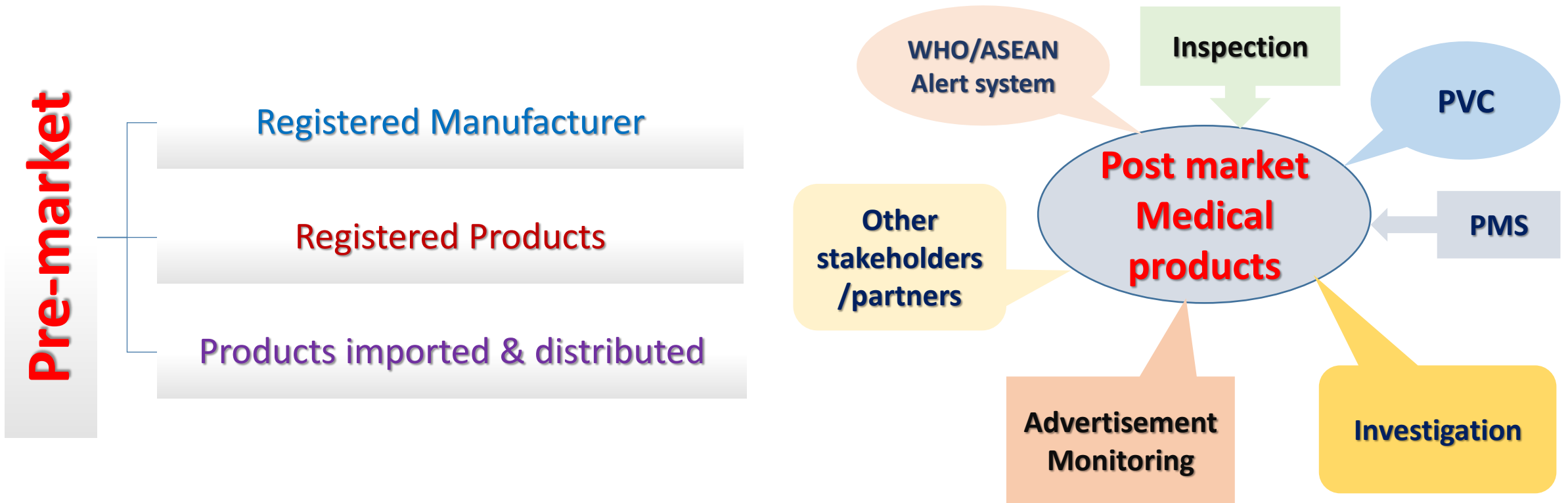
## 5. Structure of Inter-ministerial Committee (IMC) & Provincial Committees:

1. Ministry of Health
2. Ministry of Interior
3. Ministry of Justice
4. Ministry of Information
5. Ministry of Education
6. Ministry of Economic & Finance
7. Ministry of Commerce
8. Ministry of Agriculture, Forestry, and Fisheries
9. Municipality of Phnom Penh



# 4. Effort & Experiences in Combatting SFMs – Cont.:

## 10. Countermeasure against falsified & substandard medical products



# 4. Effort & Experiences in Combatting SFMs – Cont.:

## 11. Post-surveillance of medical products:

Year	No. sample	No. Failure	Withdrawal	Falsified
2021	50	12	1 (HS)	11 (TM:4, HS:4, Food:1 and hand Sanitizers:2)
2020	109	16	0	16 (Medicines 1, Alcohol and hand sanitizer 15)
2019	102	3	0	0
2018	137	7	1	06 (TM 3 & Food 3)

# 4. Effort & Experiences in Combatting SFMs – Cont.:

## 12. Action taken in 2020 – July 2022:

- Issued the warning letter against illegal advertisements: 228 cases, mostly with cosmetics and health supplements (alcohol, hand sanitizer, face mask, and COVID-19 therapeutics: 22 cases)
- **Penalty: 346 cases, mostly with cosmetics (alcohol, hand sanitizer, face mask unregistered: 20 cases)**
- **Crack down: 118 cases, mostly with cosmetics and health supplements (unregistered PPE, alcohol, hand sanitizer, COVID-19 therapeutics, rapid test for SARS-CoV-2 antigen test : 20 cases)**
- **Destroyed around 2 tons of unregistered medicines (from 2021 up to July 2022, mostly traditional medicines, and health supplements)**



# 4. Effort & Experiences in Combatting SFMs – Cont.:

## 12. Action taken in 2021 – Cont.:

### a). Conducted Inspection



### b). Crack Down of unregistered medical products





# 4. Effort & Experiences in Combatting SFMs – Cont.:

## 12. Action taken in 2021 – Cont.:

### c). Collaboration with other agencies





# 4. Effort & Experiences in Combatting SFMs – Cont.:

## 12. Action taken in 2021 – Cont.: d). Conduct PMS funded by DDF/MoH :

❖ Food product but containing **Tadalafil**



06-07/09/2022

❖ Food product but containing **Sildenafil Citrate**



Public Health Dangers: Substandard & Falsified Medicines by ORV

❖ Traditional medicine but containing:  
- **Dexamethasone 0.753mg** and  
- **Cyproheptadine 1.413mg** per capsule



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# 5. Challenges and Way Forward:

## 5.1. Challenges :

- Limited local, international & stakeholders collaboration and cooperation
- Insufficient HR skills & capacity for QC and regulations & lack of supports
- Different practices on GMP, GDP, GSP & GPP.....
- **Increasing online sells and advertising of medical products.**
- Attitude and behaviour on self-benefits rather than public health risks
- Responsibility and accountability among producers, importers/distributors/drug sellers, regulators, and consumers
- Difficult to manage the online advertisements and sells

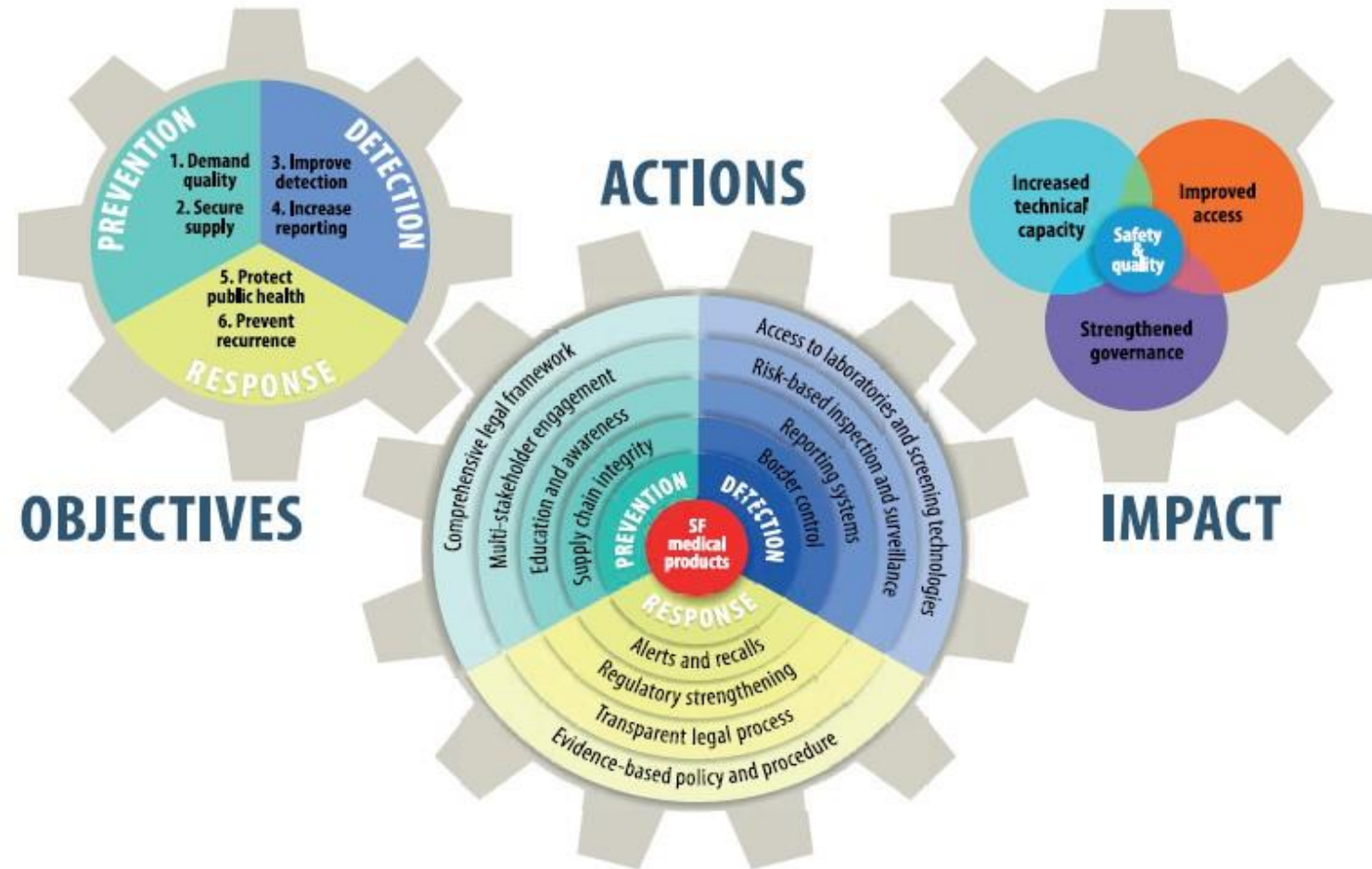
# 5. Challenges and Way Forward – Con.t :

## 5.2. Way Forward : *require our concerted effort & commitment in combatting SFMs*

- ❖ To strengthen the local & regional collaboration especially the bordering countries.
- ❖ To continue to build capacity in detection, reporting, and response
- ❖ To strengthen and promote the regular conduct of post marketing inspections and surveillance.
- ❖ To improve law enforcement and regulations online sells and advertisements
- ❖ To sharing information about SFMs through established and/or existing network for combatting SFMs among stakeholders & countries in the region.
- ❖ To enhance capacity for Quality Control and collaboration with WHO & other related stakeholders.
- ❖ To raise public awareness of the dangers of SFMs & encouraging community participation.
- ❖ To disseminate information to improve the knowledge of GXP (GMP, GSP, GPP.....) to related authorities & stakeholders.
- ❖ Multi-stakeholders engagement is important & much more needed to advance the progress of working together to combat SFMs.



# THANK YOU FOR YOUR KIND ATTENTION!!



\*S&F : substandard and falsified medical products

Source: *Global Surveillance and Monitoring System for Substandard and Falsified Medical Products, WHO.*  
<https://www.drugtrackandtrace.com/solution-for-the-substandard-and-counterfeit-medicines/>