WEEKLY EPIDEMIOLOGICAL REPORT

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WEEKLY EPIDEMIOLOGICAL REPORT SRI LANKA 2022

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Substandard and falsified medical products

Overview

Substandard and falsified medical products can harm the lives of patients and may not treat the disease for which they are prescribed. They lead to a loss of confidence in medicines, healthcare providers, and health systems. This issue can be seen all over the world. WHO has recognized different kinds of substandard medical products including drugs, vaccines, and in vitro diagnostics. Substandard antimalarial drugs and antibiotics are frequently reported. Even both generic and innovator medicine can be falsified ranging from very expensive anti-cancer chemotherapy to non-expensive pain killers. They can be sold in street markets and issued by unregulated pharmacies and hospitals. Even via illegal websites. An estimated 1 in 10 medical products in low- and middle-income countries are substandard or falsified.

These falsified medical products may contain no active products, the wrong active ingredient, or the wrong amount of the correct active ingredient. Sometimes they contain potato starch, corn starch, or chalk-like substances. Sometimes they may be fatal either due to toxic ingredients or fatal levels of the wrong active ingredients.

Substandard and falsified medical products are often made in poor and unhygienic conditions by unqualified people and they may be contaminated with bacteria. They produce them with a similar appearance to genuine products. So the detection of these fake products is not easy. Sometimes there may not be obvious adverse reactions. But the disease may not be cured by them. Hence, serious consequences to health can occur including death.

Definitions

Substandard also called "out of specification", are the authorized medical products that fail to meet either their quality standards or specifications or both.

Unregistered/unlicensed medical products that have not undergone evaluation and/or approval by the National or Regional Regulatory Authority for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.

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

How do identify substandard or falsified medical products?

Most of the time, falsified medical products are made in a similar appearance to the original licensed product. So the detection is not easy. But in the following means, we can identify them.

- Examine the packaging for quality, spelling, and grammar.
- Checking the manufacturing date, expiry date, and batch number, comparing them on the outer package and the inner package for discrepancies.
- Ensuring that the medicine has its usual medical look and is not discoloured, and also checking for an unusual smell.
- Discuss with the doctor, pharmacist, or any health care professional once notice that no improvement of the disease or adverse reaction is noted.
- Report suspicious medicine to relevant authorities

Substandard and falsified medical products and the internet.

The selling of substandard and falsified medical products is often conducted through unauthorized websites, mobile applications, and some social media platforms.

Consumers should be cautious about the following factors to avoid the harmful effects of medicines bought on the internet.

- Spam email advertising medicines
- lack of authenticity; no verification

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logo or certificate
- wrong spelling and grammar errors on the pack
- Websites that display wrong addresses or landline numbers or websites that don't display that information.
- websites that issue medicine without a prescription or bill
- suspiciously low-priced products
- The generic name of the medicine is not mentioned
- no guarantee for equipment

Checklist for medicine that is ordered online

- Is it exactly the medicine ordered? _ need to check with the generic name
- Is it the correct dosage?
- Is the condition of the package in good condition and is the patient information leaflet issued with the language that advertised it?
- Does the medicine look and smell as it should? Any abnormal smell or texture?
- Is there a seal of the relevant pharmacy or institute on the prescription or bill?
- Does any postal label declare that the parcel is medicine?
- Are the expiratory date and the batch number matching in both internal and external covers?
- Any unusual activity on the credit card after purchasing it?

Who is at risk?

Now the availability of manufacturing facilities like tableting machines, ovens, ingredients, and packing materials and technical knowledge is high. Therefore it is easy to assemble falsified drugs and medical equipment for fraud. It can be seen in many countries in all regions. Large and small-scale operations to reveal substandard and falsified drug manufacturers are frequently seen in media in many countries.

The effects of substandard and falsified drugs

- Misleading clinicians – individual patients have much to lose from substandard drugs. Doctors prescribe drugs to cure diseases, relieve symptoms, and slow the progression of diseases. When prescribing medicines with known efficacy, potency, and adverse effects, clinicians can detect misdiagnosing, inadequate dosing, and drug resistance if the expected outcome is not achieved. But if the patient has taken falsified medicine, it misleads the clinical decisions.

- Treatment failure – Patients may not achieve the expected clinical outcome when they take drugs that have low doses of ingredients. When the active ingredients of the drug are low, the circulatory level of the drug is also low. This leads to treatment failure and drug-resistant in the patient. Therefore patients may develop more complications of their diseases and the disease stage also will be gone up. Patients also may tend to give up on treatment as they don't feel any comfort.

- Antimicrobial resistance – when patients are treated with inadequate doses or lengths of antibiotics, antibiotic resistance can be developed. For example, the correct combination of standard quality antibiotics with adequate dosing for the weight is the main principle of directly observed treatment therapy in tuberculosis. To ensure that, there should be a continuous quality-assured drug supply. Poor quality drugs have been sites as a cause of multi-drug resistant tuberculosis. Nowadays, MDR TB is an emerging health issue in most parts of the world. And also drug-resistant bacteria are increasing in the hospital setting. Methicillin-resistant Staphylococcus aureus is a good example.

- Malaria and other anti-parasitic drugs are resistant - by a similar mechanism to antibiotics, some parasites have developed resistance against drugs. Artemisinin combination treatment is very effective against Malaria. But resistance has emerged through substandard drugs that contain low dosing of active ingredients. A recent review estimates that about 35 per cent of the antimalarial medicines in Southeast Asia are substandard, and 36 per cent can be classified as falsified. If the current first-line therapy is disturbed, malaria outbreaks will occur and the death toll will be increased.

- Economic and social consequences

* Usage of substandard and falsified drugs wastes time and money, patients could give up on medicine
* Society has to bear the cost of new drug development as a result of drug resistance
* Patients will distrust the healthcare system, as well as pharmacies and healthcare workers will lose confidence in medicine.
* The sale of falsified medicines funs criminals and influences corrupted officials.

Actions that need to take to prevent substandard and falsified drugs

In 2013, WHO launched the Global Surveillance and Monitoring System to encourage countries to report incidents of substandard and falsified medical products in a structured and systematic format, to help develop a more accurate and validated assessment of the problem.

The system**:**

* Links incidents between countries and regions and issues WHO medical product alerts
* Collect evidence of the harm caused by substandard and falsified medical products and identify vulnerabilities and trends.

Further, WHO has given training to a global network of staff from 141 member states to report substandard and falsified medical products to the WHO Global Surveillance and Monitoring system.

Community awareness program on substandard and falsified medical products is also an important aspect.

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References

https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products

Table 1: Selected notifiable diseases reported by Medical Officers of Health 20th– 26th Aug 2022 (34th Week)

RDHS	Dengue Fever		Dysentery		Encephaliti		Enteric Fever		Food Poi-		Leptospirosis		Typhus		Viral Hepa-		Human		Chickenpox		Meningitis		Leishmania-		WRCD	
	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	A	B	T*	C**
Colombo	16	9381	0	4	0	3	0	1	0	6	6	132	0	0	0	3	0	2	2	30	2	10	0	2	**15**	**96**
Gampaha	94	5592	0	5	0	1	0	1	0	12	14	122	0	0	0	8	1	4	3	35	2	31	0	28	**6**	**87**
Kalutara	74	2984	2	20	0	1	0	1	0	6	11	283	0	4	0	3	0	2	2	55	0	19	0	2	**30**	**55**
Kandy	18	3721	0	17	0	0	0	3	0	5	5	118	2	29	0	8	0	0	2	53	1	7	1	19	**12**	**99**
Matale	23	800	0	7	0	0	0	0	0	0	1	76	0	4	1	5	0	1	3	30	0	1	14	249	**18**	**100**
NuwaraEliya	7	175	0	18	0	0	0	3	1	2	2	60	0	12	0	6	0	0	0	31	0	3	0	0	**26**	**95**
Galle	50	2857	0	9	0	1	0	0	0	0	15	307	3	20	0	5	0	0	3	58	1	16	0	0	**12**	**100**
Hambantota	36	1273	0	27	0	0	0	0	0	2	8	186	0	32	0	6	0	0	0	21	1	9	13	357	**15**	**100**
Matara	44	1275	0	12	0	2	0	0	0	0	8	185	2	11	0	1	0	0	1	32	0	6	2	199	**30**	**100**
Jaffna	38	2478	1	46	0	2	0	58	2	30	1	20	3	413	0	6	0	4	1	81	0	10	0	0	**65**	**93**
Kilinochchi	4	101	0	6	0	0	0	1	0	24	0	11	0	9	0	0	0	0	0	4	0	2	0	2	**28**	**100**
Mannar	0	177	0	2	0	0	0	0	0	0	0	23	0	3	0	2	0	0	0	6	0	15	0	0	**18**	**80**
Vavuniya	2	70	0	3	0	1	0	2	0	0	1	16	0	1	0	0	0	0	4	27	0	0	0	4	**1**	**99**
Mullaitivu	1	51	0	4	0	0	0	2	1	6	1	25	0	5	0	0	0	0	0	6	0	1	0	1	**20**	**94**
Batticaloa	13	1016	0	48	0	7	0	0	0	20	2	36	0	0	0	1	0	1	0	24	0	29	0	1	**38**	**99**
Ampara	0	134	0	10	0	1	0	0	0	17	1	84	0	1	0	1	0	0	2	40	1	19	0	12	**12**	**95**
Trincomalee	1	991	0	23	0	0	0	1	0	2	0	22	0	3	0	4	0	0	0	32	0	6	0	1	**17**	**87**
Kurunegala	30	2113	1	18	0	2	0	0	0	4	5	116	0	24	0	1	0	1	2	65	0	29	3	339	**9**	**96**
Puttalam	33	1609	0	3	0	0	0	0	0	0	0	20	0	7	0	0	0	0	0	10	1	23	0	4	**15**	**92**
Anuradhapur	6	326	0	8	0	2	0	1	0	5	2	129	0	19	0	2	0	1	2	46	1	33	1	278	**10**	**85**
Polonnaruwa	3	117	0	6	0	0	0	0	0	1	1	93	0	0	0	3	0	0	1	14	0	3	6	334	**15**	**95**
Badulla	21	823	0	18	0	2	0	1	0	13	8	167	2	40	5	109	0	0	1	41	0	11	0	17	**16**	**100**
Monaragala	7	375	0	6	0	1	0	4	0	3	1	231	1	21	4	43	0	0	3	47	0	35	4	105	**11**	**100**
Ratnapura	36	2259	1	34	0	6	0	3	0	27	11	702	0	20	1	21	0	0	1	60	0	46	1	150	**13**	**93**
Kegalle	93	2186	0	12	2	8	0	1	3	8	9	375	0	17	0	6	0	0	4	77	0	38	1	17	**9**	**99**
Kalmune	35	840	2	27	0	1	0	1	0	6	1	20	0	1	0	1	0	0	0	46	0	31	0	0	**30**	**100**
SRILANKA	**99**	**43724**	**7**	**393**	**2**	**41**	**0**	**84**	**7**	**199**	**11**	**3559**	**13**	**696**	**11**	**245**	**1**	**16**	**37**	**971**	**10**	**433**	**46**	**2121**	**18**	**95**

Source: Weekly Returns of Communicable Diseases (esurvillance.epid.gov.lk). T=Timeliness refers to returns received on or before 26th Aug , 2022 Total number of reporting units 361 Number of reporting units data provided for the current week: 284 **C****-Completeness

Table 2: Vaccine-Preventable Diseases & AFP

20th– 26th Aug 2022 (34th Week)

Disease	No. of Cases by Province									Number of cases during current week in 2022	Number of cases during same week in 2021	Total number of cases to date in 2022	Total number of cases to date in 2021	Difference between the number of cases to date in 2022 & 2021
	W	C	S	N	E	NW	NC	U	Sab					
AFP*	00	00	00	01	00	01	00	00	00	02	02	53	38	39.4 %
Diphtheria	00	00	00	00	00	00	00	00	00	00	00	00	00	0 %
Mumps	00	01	00	01	01	00	00	00	00	03	01	57	57	0 %
Measles	00	00	00	00	00	00	00	00	00	00	00	16	11	45.4 %
Rubella	00	00	00	00	00	00	00	00	00	00	00	00	00	0 %
CRS**	00	00	00	00	00	00	00	00	00	00	00	00	00	0 %
Tetanus	00	00	00	00	00	00	00	00	00	00	00	05	02	150 %
Neonatal Tetanus	00	00	00	00	00	00	00	00	00	00	00	00	00	0 %
Japanese Encephalitis	00	00	00	00	00	00	00	00	00	00	00	01	03	- 66.6 %
Whooping Cough	00	00	00	00	00	00	00	00	00	00	00	01	00	0 %
Tuberculosis	193	176	06	16	13	20	00	13	36	473	86	4110	3429	19.8 %

Key to Table 1 & 2

Provinces: **W**: Western, **C**: Central, **S**: Southern, **N**: North, **E**: East, **NC**: North Central, **NW**: North Western, **U**: Uva, **Sab**: Sabaragamuwa.

RDHS Divisions: **CB**: Colombo, **GM**: Gampaha, **KL**: Kalutara, **KD**: Kandy, **ML**: Matale, **NE**: Nuwara Eliya, **GL**: Galle, **HB**: Hambantota, **MT**: Matara, **JF**: Jaffna, **KN**: Killinochchi, **MN**: Mannar, **VA**: Vavuniya, **MU**: Mullaitivu, **BT**: Batticaloa, **AM**: Ampara, **TR**: Trincomalee, **KM**: Kalmunai, **KR**: Kurunegala, **PU**: Puttalam, **AP**: Anuradhapura, **PO**: Polonnaruwa, **BD**: Badulla, **MO**: Moneragala, **RP**: Ratnapura, **KG**: Kegalle.

Data Sources:

Weekly Return of Communicable Diseases: Diphtheria, Measles, Tetanus, Neonatal Tetanus, Whooping Cough, Chickenpox, Meningitis, Mumps., Rubella, CRS,

Special Surveillance: AFP* (Acute Flaccid Paralysis), Japanese Encephalitis

CRS =**Congenital Rubella Syndrome

NA = Not Available

Number of Malaria Cases Up to End of August 2022,

03

All are Imported!!!

Comments and contributions for publication in the WER Sri Lanka are welcome. However, the editor reserves the right to accept or reject items for publication. All correspondence should be mailed to The Editor, WER Sri Lanka, Epidemiological Unit, P.O. Box 1567, Colombo or sent by E-mail to **chepid@sltnet.lk. Prior approval should be obtained from the Epidemiology Unit before publishing data in this publication**

ON STATE SERVICE

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