WEEKLY EPIDEMIOLOGICAL REPORT

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231, de Saram Place, Colombo 01000, Sri Lanka
Tele: + 94 11 2695112, Fax: +94 11 2696583, E mail: epidunit@sltnet.lk
Epidemiologist: +94 11 2681548, E mail: chepid@sltnet.lk
Web: http://www.epid.gov.lk

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Pharmacovigilance of Medicines and Medical Devices

Medicines and vaccines reshaped the treatment and prevention of diseases. However, the benefits of any medicinal products have potential side effects, some of which are undesirable and unexpected. While all medicines and vaccines undergo stringent testing for safety and efficacy during preclinical studies and clinical trials (before being licensed for use), such studies are done among small selected populations and during relatively short periods. Therefore, some side effects may remain undetected and appear only when such products are used by a large and diverse population including, people with co-morbidities, pregnant females, elderly persons, etc. Pharmacovigilance (a.k.a. post-licensure or post-marketing surveillance) is a scientific discipline that includes all activities concerning the detection, assessment, understanding and prevention of adverse effects of medicinal products, devices or vaccines and is the "ongoing process of monitoring the safety and effectiveness of drugs, medical devices, vaccines, and other medical products after they have been approved and are available on the market". The goal of pharmacovigilance is to ensure the safe and effective use of medicines by identifying and minimizing risks while maximizing benefits.

Key aspects of pharmacovigilance include,

Adverse Event Reporting: healthcare professionals, patients, and manufacturers are encouraged to report any adverse events, side effects, or unexpected outcomes associated with a particular medical product;

Signal Detection: involves analyzing collected data to identify potential safety signals (i.e. patterns or trends that might indicate previously unrecognized safety concerns that trigger further investigation);

Benefit to Risk Assessment and Management: helps regulators and manufacturers to continually assess the benefit-risk balance of a medical product, when a potential safety concern is identified, (regulators and manufacturers assess the risk and determine the appropriate actions, including product recalls or other regulatory interventions) As new safety concerns emerge, the product's labeling is updated to reflect the current information and to provide healthcare professionals and the public with appropriate guidance;

Surveillance Systems: are established in many countries to collect, analyze and manage post-market data from a variety of sources.

Figure 1: The pharmacovigilance cycles

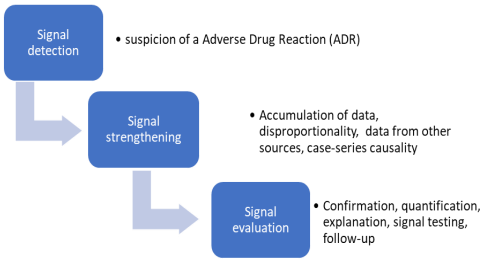

Figure 2: Steps in signal detection

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A robust system for pharmacovigilance is an obligation of the governing bodies to fulfil the responsibilities of monitoring the safety of licensed medicinal products. The pharmacovigilance cycle includes the identification of adverse events, notification and reporting using standard tools, followed by investigation, determining causality, feedback and communication. National and international guidelines for post-marketing surveillance provide a structured framework for pharmaceutical companies, regulatory authorities, healthcare professionals, and other stakeholders to monitor the safety and effectiveness of marketed medical products effectively.

Tools and innovations in the pipeline for pharmacovigilance include Artificial Intelligence (AI) and Machine Learning models that can predict potential adverse events based on patient profiles, medical history and genetic makeup. Additional algorithms are being developed that could identify patterns and associations between medications and adverse events that are not immediately obvious. The World Health Organization (WHO) is collaborating to develop databases and dashboards, to allow researchers, healthcare professionals and government officials to collaborate and share anonymized data across borders to detect critical global safety trends to address safety signals rapidly and for monitoring and evaluation of national pharmacovigilance systems. The WHO Program for International Drug Monitoring (WHO PIDM) has developed advanced statistical algorithms to detect adverse events more effectively (e.g. VigiBase platform incorporates Bayesian modeling and data mining to enhance signal detection capabilities). Additional trials are underway to use the free text field in VigiFlow to implement Natural Language Processing (NLP) to extract relevant meaningful information from unstructured text in electronic health records and medical notes.

Pharmacovigilance in Sri Lanka

A key element of Sri Lanka's health strategy is guaranteeing a sufficient supply of safe and efficient medications and medical equipment. The National Medicinal Drug Regulatory Authority (NMRA) determines whether medications and cosmetics comply with minimum requirements i.e., Considering the WHO's Good Manufacturing Practices (GMPs) as the gold standard. Every two years, all local manufacturers undergo routine inspections whilst, international manufacturers provide an attestation confirming compliance with GMPs from a government-authorized entity. The primary organization responsible for guaranteeing the quality of all pharmaceuticals, medical equipment, cosmetics, and borderline goods registered with the NMRA is the National Drug Quality Assurance Laboratory (NDQAL). Before granting registration, during premarketing, and after marketing, the NDQAL examines all products that are produced in or imported into Sri Lanka. Analysis of efficacy, safety, and quality are carried out with verified testing methods in compliance with pharmacopeia requirements.

In 1999, the Department of Pharmacology, Faculty of Medicine, University of Colombo founded the Drug Information Service and Monitoring of ADRs Unit, or INFO-VIG, in partnership with the Ministry of Health and in 2001, Sri Lanka was admitted as the 59th member of the World Health Organization's Drug Monitoring Program. Currently, ADRs are reported to the Director General/CEO of the National Medicinal Drug Regulatory Authority (NMRA) using a standard case reporting form that is available online as well as at institutions. The NMRA urges physicians, dentists, pharmacists, and nurses to use these standard forms to report ADRs related to medications and medical devices. A separate reporting form has been made available to report drug-induced anaphylaxis.

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Suspected Adverse Reaction to Medicines / Borderline Products - https://nmra.gov.lk/images/PDF/suspected_adverse_reaction_to_medicinesborderline_products.pdf

Anaphylaxis Case Reporting Form – https://nmra.gov.lk/images/PDF/anaphylaxis-case-reporting-form.pdf

Compiled by

Dr. Rimaza Niyas (Senior Registrar)
Epidemiology Unit.

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 to be continued….

Table 1: Selected notifiable diseases reported by Medical Officers of Health 02nd– 08th Dec 2023 (49th Week)

RDHS	Dengue Fever		Dysentery		Encephali		Enteric F.		Food Poi-		Leptospirosis		Typhus		V. Hep.		H. Rabi.		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	450	13832	0	16	0	18	0	4	0	12	5	354	0	0	0	6	0	0	5	365	3	49	0	7	**41**	**100**
Gampaha	192	12899	0	21	0	21	0	13	12	26	15	606	0	12	0	20	0	0	6	300	0	128	2	48	**11**	**99**
Kalutara	85	4547	1	30	0	5	0	1	0	19	26	861	0	2	0	10	0	1	19	543	4	101	0	4	**33**	**100**
Kandy	469	7930	1	42	0	3	0	11	0	23	5	299	0	64	0	5	0	2	9	326	1	31	0	36	**83**	**100**
Matale	61	1850	0	5	0	3	0	1	0	39	3	142	0	14	0	8	0	0	3	75	0	10	4	342	**25**	**100**
NuwaraEliya	26	350	3	161	1	6	0	3	0	51	2	189	1	76	0	6	0	0	8	214	0	34	0	3	**58**	**100**
Galle	154	3266	0	53	0	15	0	6	1	43	35	932	7	80	0	2	0	1	13	377	1	34	0	3	**36**	**100**
Hambantota	55	1437	0	17	0	4	0	1	1	10	12	352	0	69	0	9	0	0	2	152	0	19	9	646	**31**	**100**
Matara	37	1903	0	29	1	10	0	1	0	69	12	536	0	34	0	7	0	2	9	311	0	24	1	183	**54**	**100**
Jaffna	311	2995	6	160	0	2	1	17	1	46	2	16	50	615	0	8	0	2	6	198	0	20	1	3	**70**	**93**
Kilinochchi	9	119	1	23	0	0	0	1	0	18	1	11	0	8	0	1	0	0	0	19	0	2	0	0	**49**	**100**
Mannar	9	116	1	9	0	0	0	1	0	0	0	40	1	8	0	1	0	0	0	3	0	11	0	1	**56**	**100**
Vavuniya	1	188	0	14	0	1	0	0	0	26	4	43	0	10	0	3	0	0	2	36	0	17	0	11	**19**	**100**
Mullaitivu	1	129	0	16	0	1	0	5	0	12	1	40	0	7	0	1	0	0	0	19	0	2	0	8	**27**	**96**
Batticaloa	89	2456	5	229	0	11	0	5	0	19	3	115	0	2	0	8	0	4	1	145	0	50	0	1	**64**	**100**
Ampara	2	271	0	18	0	1	0	1	0	70	9	168	0	2	0	2	0	0	4	99	1	66	0	12	**15**	**100**
Trincomalee	20	2103	2	30	1	2	0	2	0	69	5	94	0	15	0	5	0	0	0	87	0	31	0	7	**30**	**99**
Kurunegala	159	3382	5	70	1	18	0	1	0	9	26	498	1	21	1	16	0	3	11	526	8	231	13	583	**28**	**100**
Puttalam	89	3313	1	50	0	5	0	1	0	2	14	128	0	9	0	1	0	0	3	129	4	94	2	27	**29**	**99**
Anuradhapur	39	793	2	18	1	2	0	1	0	12	15	305	2	35	0	5	0	2	4	243	1	51	20	707	**29**	**100**
Polonnaruwa	20	620	1	27	0	6	5	6	0	11	25	221	0	9	0	16	0	0	2	97	0	18	7	423	**37**	**99**
Badulla	174	1562	1	46	0	6	0	0	0	45	12	349	2	65	0	96	0	0	2	198	3	55	0	43	**63**	**100**
Monaragala	46	768	0	26	0	6	0	0	0	8	39	571	1	40	1	34	0	1	1	79	5	89	1	180	**29**	**100**
Ratnapura	50	2330	3	68	1	20	0	3	0	62	28	1303	0	31	1	20	0	2	9	263	1	149	0	209	**34**	**100**
Kegalle	111	3201	0	28	0	3	0	2	1	23	33	750	1	47	0	6	0	0	19	479	2	95	1	46	**34**	**100**
Kalmune	30	1753	1	73	1	13	0	0	0	4	2	63	0	1	1	1	0	0	2	183	1	45	0	0	**52**	**100**
SRILANKA	**2689**	**74113**	**34**	**1279**	**7**	**182**	**6**	**87**	**16**	**728**	**334**	**8986**	**66**	**1276**	**4**	**297**	**0**	**20**	**140**	**5466**	**35**	**1456**	**61**	**3533**	**41**	**99**

Source: Weekly Returns of Communicable Diseases (esurvillance.epid.gov.lk). T=Timeliness refers to returns received on or before 08th Dec, 2023 Total number of reporting units 358 Number of reporting units data provided for the current week: 350**C****-Completeness *

A = Cases reported during the current week. B = Cumulative cases for the year.

Table 2: Vaccine-Preventable Diseases & AFP

02nd– 08th Dec 2023 (49th Week)

Disease	No. of Cases by Province									Number of cases during current week in 2023	Number of cases during same week in 2022	Total number of cases to date in 2023	Total number of cases to date in 2022	Difference between the number of cases to date in 2023 & 2022
	W	C	S	N	E	NW	NC	U	Sab					
AFP*	01	00	00	00	00	00	00	01	00	02	02	92	80	15 %
Diphtheria	00	00	00	00	00	00	00	00	00	00	00	00	00	0 %
Mumps	00	00	00	00	00	00	00	01	00	01	05	220	93	136.5 %
Measles	08	02	02	02	00	02	01	00	00	17	01	774	37	1991.8 %
Rubella	00	00	00	00	00	00	00	00	00	00	00	09	00	0 %
CRS**	00	00	00	00	00	00	00	00	00	00	00	02	00	0 %
Tetanus	00	00	00	00	00	00	00	00	00	00	00	06	05	20 %
Neonatal Tetanus	00	00	00	00	00	00	00	00	00	00	00	00	00	0 %
Japanese Enceph-alitis	00	00	00	00	00	00	00	00	00	00	02	06	14	-57.1 %
Whooping Cough	00	00	00	00	00	00	00	00	00	00	00	07	01	600 %
Tuberculosis	77	22	15	11	11	20	08	07	10	181	19	8722	6186	40.99%

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

Take prophylaxis medications for leptospirosis during the paddy cultivation and harvesting seasons.

It is provided free by the MOH office / Public Health Inspectors.

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

Dr. Samitha Ginige
Actg. CHIEF EPIDEMIOLOGIST
EPIDEMIOLOGY UNIT
231, DE SARAM PLACE
COLOMBO 10